Medserena Upright MRI Centre

Quality Report

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Date of inspection visit: 8 August 2018 and 15 August 2018
Date of publication: 27/11/2018

This report describes our judgement of the quality of care at this location. It is based on a combination of what we found when we inspected and a review of all information available to CQC including information given to us from patients, the public and other organisations

Ratings

Overall rating for this location	Requires improvement
Are services safe?	Requires improvement
Are services effective?	
Are services caring?	Good
Are services responsive?	Good
Are services well-led?	Requires improvement

Overall summary

Medserena Upright MRI Centre is operated by Medserena Upright MRI LTD.

Medserena Upright MRI Centre is in Manchester. It was opened in November 2017 and provides upright magnetic resonance imaging scans to adults and children over 12 years old. The service is located on the ground floor and facilities include one magnetic resonance imaging scanner, two changing areas, a waiting area and two consulting rooms.

Summary of findings

We inspected the service in Manchester using our new phase inspection methodology. We carried out an unannounced part of the inspection on 8 August 2018, along with an announced visit on 15 August 2018.

To get to the heart of patients' experiences of care and treatment, we ask the same five questions of all services: are they safe, effective, caring, responsive to people's needs, and well-led? Where we have a legal duty to do so we rate services' performance against each key question as outstanding, good, requires improvement or inadequate.

Throughout the inspection, we took account of what people told us and how the provider understood and complied with the Mental Capacity Act 2005.

This is the first time we have inspected Medserena Upright MRI Centre, Manchester, therefore we have not previously rated this service. We rated it as requires Improvement overall.

We found areas of practice that require improvement:

- The service was not able to demonstrate that there was a robust recruitment process to ensure staff employed were 'fit and proper' for their role.
- The service did not have systems in place to document and demonstrate risks had been identified, and that actions were taken to mitigate risk or monitored.
- Policies and procedures were not robust and did not always reflect current guidance.
- There was no evidence of an effective process in assessing, monitoring and improving the service.
- Not all staff received mandatory training.
- Records were not stored securely.

We also found the following areas of good practice:

- The service had suitable premises and equipment that were maintained and well looked after.
- Staff assessed and responded to patient risk.
- The service planned and offered services in a way that met the needs of the local people.
- Staff treated patients with care and compassion.

Following this inspection, we told the provider that it must take some actions to comply with the regulations and that it should make other improvements, even though a regulation had not been breached, to help the service improve. We also issued the provider with four requirement notices. Details are at the end of the report.

Ellen Armistead

Deputy Chief Inspector of Hospitals (North)

Summary of findings

Our judgements about each of the main services

Service	Rating	Summary of each main service
Location	Requires improvement 	
Diagnostic imaging	Requires improvement 	The service was not able to demonstrate that there was a robust recruitment process to ensure staff employed were 'fit and proper' for their role. The service did not have systems in place to document and demonstrate risks had been identified, and that actions were taken to mitigate risk or monitored. Policies and procedures were not robust and did not always reflect current guidance. There was no evidence of an effective process in assessing, monitoring and improving the service. Not all staff received mandatory training. Records were not stored securely. However, the service had suitable premises and equipment that were maintained and well looked after. Staff assessed and responded to patient risk. The service planned and offered services in a way that met the needs of the local people. Staff treated patients with care and compassion.

Summary of findings

Contents

Requires improvement

Medserena Upright MRI Centre

Services we looked at:
Diagnostic imaging

Summary of this inspection

Background to Medserena Upright MRI Centre

Medserena Upright MRI Centre is operated by Medserena Upright MRI LTD. The service opened in November 2017 and provides upright magnetic resonance imaging scans to NHS, private insurance, private healthcare and self-paying patients.

It is one of two services owned by Medserena Upright MRI LTD - the other service is based in London.

The location has had a registered manager in post since November 2017.

Our inspection team

The team that inspected the service comprised a CQC lead inspector,one other CQC inspector, and a specialist advisor with expertise in radiology. The inspection team was overseen by Nicholas Smith, Head of Hospital Inspection.

Information about Medserena Upright MRI Centre

Medserena Upright MRI Centre is registered to provide the following regulated activities:

- Diagnostic and screening procedures

During the inspection we spoke with six staff including; radiographers, administration staff and senior managers. During our inspection, we reviewed 29 patient safety questionnaires, we spoke to two patients and observed care.

There were no special reviews or investigations of the location ongoing by the CQC at any time during the 12 months before this inspection. This service has not previously been inspected.

Activity during the reporting period (November 2017 to July 2018):

- There were 154 patients including NHS patients, private healthcare patients and self-funding patients who had attended the service.

At the location there was one radiographer, one receptionist and a service development executive who each worked full time. There were eight radiologists who worked remotely for the provider under reporting privileges.

Track record on safety

- No Never events
- No clinical incidents
- No serious injuries

Medserena Upright MRI Centre had received one complaint in relation to staff behaviour.

There were no services provided at the location under service level agreement.

Summary of this inspection

The five questions we ask about services and what we found

We always ask the following five questions of services.

Are services safe?

Requires improvement

Are services safe?

We rated safe as requires improvement because:

- The service did not monitor compliance or consistently provide mandatory training to all staff and staff had not received appropriate training relevant to their designated role.
- There was no lone worker policy or risk assessments to minimise any potential risks to staff who worked in isolation.
- There was no documented evidence that incidents were investigated, actions were taken or lessons learned were shared across the provider.
- Patient records were not stored within a secure environment.
- Not all staff knew how to switch off the scanner in an emergency.

However

- The service had suitable premises and equipment which were maintained and looked after them well.
- Staff assessed and responded to patient risk.
- Staff understood how to escalate concerns to protect patients from abuse.

Are services effective?

Are services effective?

We do not rate effective however areas of good practice:

- Staff assessed and monitored patients regularly to see if they were in pain.
- There was good interaction between staff of all levels.
- Staff understood how and when to assess whether a patient had the capacity to make decisions about their care.

However

- There was no formal assessment to ensure staff were competent for their roles.
- Policies in place did not make reference to current guidance for staff to follow.

Are services caring?

Good

Are services caring?

Summary of this inspection

We rated caring as good because:

- Staff cared for patients with compassion.
- Feedback from patients confirmed that staff treated them well and with kindness.
- Staff emotionally supported to patients to minimise their distress or anxiety.

Are services responsive?

Good

Are services responsive?

We rated responsive as good because:

- The provider planned and offered services in a way that met the needs of local people.
- People could access the service when they needed it.
- The service treated concerns and complaints seriously and investigated them.

However

- The service did not always take account of and respond to patients' individual needs.

Are services well-led?

Requires improvement

Are services well-led?

We rated well-led as requires improvement because:

- The service did not demonstrate that processes were in place to ensure all staff employed were of good character, had the right competencies and skills and were physically and mentally fit for their role.
- The service did not have systems in place to document and demonstrate risks had been identified, actions taken to mitigate risk or that they were monitored.
- Policies did not provide clear guidelines for staff to follow.
- There was no evidence of effective governance including assessing and monitoring of performance.

However

- All staff were aware of the vision for the service.
- Staff felt supported and valued and there was an open and honest culture.
- The service engaged with patients following their scan to receive initial feedback of their experience.

Detailed findings from this inspection

Overview of ratings

Our ratings for this location are:

	Safe	Effective	Caring	Responsive	Well-led	Overall
Diagnostic imaging	Requires improvement	N/A	Good	Good	Requires improvement	Requires improvement
Overall	Requires improvement	N/A	Good	Good	Requires improvement	Requires improvement

Requires improvement

Diagnostic imaging

Safe	Requires improvement
Effective	
Caring	Good
Responsive	Good
Well-led	Requires improvement

Are diagnostic imaging services safe?

Requires improvement

We have not previously inspected this location. We rated it as requires improvement.

Mandatory training

- Prior to inspection the provider did not submit any data relating to mandatory training modules or compliance.
- The manager told us that none of the administration staff had received mandatory training. However, their public facing role means that several of the mandatory training course were relevant.
- The managing director confirmed radiographers attended mandatory training, which was facilitated by an external provider. At the time of inspection one radiographer had not completed basic life support for children. We raised this with senior managers at the time of inspection and following our inspection we received data that to confirm the radiographer has completed children's life support training levels one and two on 29 August 2018.

Safeguarding

- The service had a designated safeguarding lead, who was based at another location and had completed levels one and two in both safeguarding vulnerable adults and safeguarding vulnerable children. Not all the staff knew who this was.
- Data provided prior to inspection stated all staff involved in patient care were trained in levels one and two in adults safeguarding and level one to three in children's safeguarding. However, following our inspection evidence showed the service development executive had completed and administrative staff had partially completed an online safeguarding module and it wasn't clear whether this was level one, which is what they were required to complete.
- Staff did not have access to a designated person who had completed level three safeguarding children's training. We raised this with the managing director at the time of inspection. However, since the inspection we have been provided with evidence that the radiographer had completed level two and three in safeguarding of vulnerable adults and safeguarding vulnerable children.
- There was a safeguarding service users from abuse and improper treatment standard operating procedure for staff to follow. The procedure did not reference types of abuse; individual's roles or responsibilities; what staff should do if a person discloses they are being abused or they suspect abuse; also, the contact details of the designated safeguarding person within the service or the local authority were not included.
- Following our unannounced inspection, we were provided with a refreshed safeguarding policy. The policy described different types of abuse. There were no contact details for the local authority safeguarding children's and adult's boards or the company safeguarding lead were not included.
- During our inspection, staff we spoke to understood their responsibilities around keeping patients safe and told us they would escalate any concerns they had to either the radiographer or their manager.
- The 'pause and check' is used by practioners in clinical imaging services to act as a reminder of checks required when a scan is required. During our inspection we observed the radiographer adhere to the 'pause and check' and they were aware of the importance of its use.

Cleanliness, infection control and hygiene

Diagnostic imaging

- All patient areas that we visited were visibly clean and clutter-free. All equipment was also observed to be visibly clean.
- Guidelines regarding cleanliness was documented within the safe care and treatment standard operating procedure, which also stated staff would be provided with ongoing training and refresher course in infection control. Data provided showed the radiographer and their manager had attended infection control training.
- Patients and staff had access to hand gel and during our inspection we observed staff washing their hands and cleaning equipment before and after patient care.

Environment and equipment

- The magnetic resonance imaging equipment complied with medicines and healthcare products regulatory agency recommendations except for the entrance to the control room. This did not have a locking mechanism and there was no panic alarm system within the magnetic resonance imaging suite. We raised this at the time of inspection.
- Emergency pull cords were positioned within the patient changing rooms. However, there were no emergency button within the scanning area to call for assistance in an emergency. The safeguarding patients from abuse standard operating procedure and safe care and treatment policy both stated alarms were positioned in scanning areas.
- Data provided showed maintenance checks had been completed on equipment and the environment within the scanning area.
- Quality checks on equipment were performed daily by the radiographer using a phantom scanner. This is a specially designed quality assurance device that is scanned in the magnetic resonance imaging field of view to evaluate, analyse, and tune the performance of the scanner. We observed a daily checklist which confirmed quality assurance checks had been completed daily, prior to patients attending, for the previous three months.
- Equipment required for performing a scan was available and included a wheelchair which could be used, if required, within the scanning area.
- We were provided with data which showed a fire risk assessment of the location had been completed in January 2018. Monthly automatic door release and fire alarm tests had been performed at the location. The risk assessment identified that fire safety was managed by the receptionist and fire awareness and marshal training was being addressed. However, when we spoke to the receptionist they were unaware of their responsibilities and had not attended any training.

Assessing and responding to patient risk

- The magnetic resonance imaging scan could be switched off throughout the day if required and we were told it was always turned off overnight. In addition, there was an emergency switch off button located outside the scanning area and near the reception desk. The radiographer told us they would shout to the administration staff who had been trained to use the emergency button if required. The service development worker was providing cover whilst the administration staff was on annual leave. During our inspection we asked the service development executive and they were not aware of how to use the emergency button.
- Patients had access to an alarm whilst in the scanner. There was a large window which the radiographer said they used this to visually monitor the patient at all times.
- The administration staff told us when they telephoned patients to arrange an appointment, they asked patients about potential risks, for example any metal fragments in the body, patients weight or specific medical conditions such as epilepsy and any concerns would be escalated to the radiographer, who would if required, contact the patient.
- The administration staff told us they had not been given a checklist to use so had devised their own checklist using questions documented in the patient questionnaire to use as a prompt when phoning patients. Following our inspection, we were provided with a phone appointment checklist which was not the same as the one observed during the inspection. On our return visit to the site we observed the second checklist being used by administration staff.
- Patients completed a questionnaire to identify any potential risks prior to their scan. This information was reviewed by the radiographer who discussed any risks before deciding if it was appropriate to complete the scan.
- Staff told us they were not aware of any policy or pathway to follow if a patient became unwell whilst on site. However, staff told us how they would respond to an emergency by calling the emergency services.

- Resuscitation equipment, including a defibrillator was located within the scanning area and all staff were familiar with the location. We reviewed daily checklists for the previous three months and observed these had been completed apart from on four occasions.
- The radiographer had received training on the use of the automated external defibrillation. We received data which showed the two administrative were booked onto the defibrillation course on the 21 August 2018.
- The emergency evacuation procedure was clearly documented within the reception area with clear guidance on designated assembly points away from the building.

Staffing

- There were sufficient staff deployed to meet the needs of patients using the service these include administration and clinical staff.
- The service development executive worked across all the services in the north-west region.
- The service did not utilise agency or bank staff.
- There was one full time radiographer who was based full time at the location. The radiographer worked alone and told us they had access via phone to their manager and radiologists if they required any support or guidance. The radiographer gave us examples when this had been done.
- The service did not have a lone worker policy and there were no risk assessments completed to mitigate any potential risks. The managing director told us there were no plans to employ further staff. However, this would be reviewed if patient numbers increased.
- The radiology manager covered for the radiographer when they were on leave.
- The service had eight radiologists who worked remotely under reporting privileges.

Records

- Records were fully maintained. These were paper records and consisted of patient referrals, patient safety questionnaires, and consent forms.
- The patient records were stored in an unlocked cupboard in a corridor at reception and staff told us that other records were also stored under the reception desk. This meant that unauthorised people could access patient information. We raised this during inspection and asked staff to move this. On a later visit to the location on 15 August we observed all records had been removed to a secure locked cupboard.
- We reviewed 29 patient safety questionnaires and observed seven were not fully completed. For example, four questionnaires had missing data including if the patient had missing fragments, four were answered as having metal implants but contained no further documentation to clarify if this had been discussed or followed up by the radiographer and one had no patient identification written number on. Following our inspection, the provider told us the radiographer signs and dates each form to confirm that each question had been checked and discussed, where necessary, with the patient.
- Images following the scan were sent electronically to a radiologist via the picture archiving and communication system, who then reviewed and sent the report via the radiological information system. Scans could also be viewed remotely by the clinical director. We reviewed six electronic radiological information system records and found these to be clear and completed.
- We requested a copy of the audit of records and received an audit of patient safety questionnaires completed from January to March 2018. The audit focussed on one question 'have you had any surgery of any type' and identified 14 of the 37 had answered the question with a 'yes'. However, only seven responses documented details and dates. In response to the audit, the questionnaire question was revised to make the question specific and included a timeline of three months.

Medicines

- Medicines were not regularly used in the service. However, on occasions some patients may require a scan to be completed with a medical dye that show on the scan. The medicine was stored securely.
- During our inspection we observed that an EpiPen was stored on the resuscitation trolley. This was within reach of any persons walking through the scanning room. This was raised and the EpiPen was moved immediately to a locked cupboard above the trolley.

Incidents

- The provider had reported no serious incidents or never events reported since the service had opened in

November 2017. Never events are serious patient safety incidents that should not happen if healthcare providers follow national guidance on how to prevent them. Each never event type has the potential to cause serious patient harm or death but neither need have happened for an incident to be a never event.

- Guidance for staff to follow in relation to reporting safety notifiable incidents was documented within the duty of candour standard operating procedure. Staff we spoke to were aware of the principles of duty of candour. The duty of candour is a regulatory duty that relates to openness and transparency and requires providers of health and social care services to notify patients (or other relevant persons) ofcertain 'notifiable safety incidents'andprovide reasonable support to that person.
- Incidents were reported on an electronic accident and incident form, which staff told us was sent to London to be investigated. However, staff told us they didn't receive any formal feedback.
- Two incidents had been reported from November 2017 to July 2018. One incident related to an external contractor who injured their finger and required medical attention at hospital and the other was relating to an in-patient from a nearby hospital who attended unescorted and fainted during the procedure.
- We reviewed the incidents and noted details regarding each incident were documented along with actions to be taken to prevent recurrence. There was no evidence of an investigation, that actions had been taken or sharing of lessons learned across the provider.
- Senior managers told us feedback was provided verbally. When we spoke to staff they were aware of both incidents and confirmed following the incident with the unescorted in-patient incident, they did not accept patients who were currently inpatients at other hospitals and specifically checked this when contacting the patient. We observed this was a question the administrators clarified on referral. However, we could not see anything formally documented about this.

Are diagnostic imaging services effective?

We inspected but did not rate the effective domain as we are not confident we are currently collecting enough information to rate this domain in diagnostics.

Evidence-based care and treatment

- The provider had an internal clinical audit standard operating policy which stated that 10% of patient reports in each quarter would be also be reviewed by a second independent radiologist. The review would include areas defined within the board of the faculty of clinical radiology standards for the reporting and interpretation of imaging investigations 2006 (Royal College of radiologists). The standard operating procedure stated trends would be identified and when performance should be monitored or further training would be required.
- We requested a copy of the last two audits along with action plans. However, we were only provided with eleven reports dating from quarter four. We observed that technical merit of image was reported as good in all but one report which was ticked as poor. Three records were identified as a trivial difference of opinion and one was classed as a minor disagreement. Information on the forms were brief and not always easily legible. They were signed but the name wasn't printed and it was not clear who had re-reviewed the report.

Nutrition and hydration

- Staff had access to a kitchen area and provided patients with free hot and cold drinks and biscuits.

Pain relief

- The patient information leaflet confirmed that patients should not feel any pain as a result of having a scan. However, staff acknowledged that patients attending for a scan could already be experiencing pain due to their condition.
- During our inspection we observed the radiographer stopping in between sequences to give a patient opportunity to rest and change position to reduce their pain.

Patient outcomes

- Senior managers told us the service did not monitor patient outcomes.

Competent staff

- We were provided with evidence that the radiographer had achieved qualifications in diagnostic radiography and medical imaging including medical ultrasound.

Requires improvement

Diagnostic imaging

- During our inspection we found staff were knowledgeable about the patient's pathway and their roles and responsibilities.
- Induction for staff was provided at another location and focussed on orientation to that environment for example fire exits. However, the radiographer told us they had their induction on site and was provided by their immediate line manager, who also taught and provided clinical supervision with the equipment. The following week, the radiographer was supported and supervised by a specialist in the upright scanner.
- The administration staff told us as part of their induction they received training with the booking, invoicing and electronic systems.
- We requested details from the provider regarding induction and were provided with role specific induction for the radiographer. We observed specific training in equipment to be completed. However, there were no competencies to evidence these had been met.
- The managers confirmed staff did not have competencies to complete and therefore we were not assured if staff had been deemed competent to perform their role.
- Data provided showed both administration staff had received their appraisal. As the radiographer had recently joined the organisation their appraisal was not due.

Multidisciplinary working

- During our inspection we observed good interaction and a positive working environment with the three members at the service.

Seven-day services

- The service was provided from 8.30am until 5.30pm on weekdays only.

Consent and Mental Capacity Act

- The service had a 'need for consent' standard operating procedure which stated that during the initial booking phone call the customer administrator would be able to identify if the patient lacks capacity to make their own consent decisions. In these circumstances, they must follow the guidelines in Mental Capacity Act 2005.
- The procedure also stated administration staff would follow the guidance within the British Medical Association children's and young people's tool kit if a child is under the age of 16 years. The toolkit is designed for doctors and identifies key factors which should be considered when making decisions.
- There was no reference within the procedure regarding Gillick competency guidelines. The Gillick competency and Fraser guidelines help people who work with children to balance the need to listen to children's wishes with the responsibility to keep them safe. They help clinicians assess whether a child has the maturity to make their own decisions and to understand the implications of those decisions.
- We spoke with staff and observed practice of obtaining consent. The administrator only provided the safety questionnaire and consent form to the patient for completion. The radiographer reviewed the form, discussed any areas of concern and gained consent.
- We spoke with the radiographer who demonstrated knowledge and understanding around capacity and told us if there was any doubt regarding a patient's capacity they would not perform the scan.
- Radiographers had each completed patient consent and confidentiality training as part of the information governance training and training in the Mental Capacity Act and assessing capacity was completed as part of the safeguarding adults course.
- Along with consenting to the procedure, patients were also required to consent for the scanned images and findings to be sent to the referring clinician or GP.

Are diagnostic imaging services caring?

Good

We have not previously inspected this location. We rated it as good.

Compassionate care

- Patients were respected and their privacy and dignity was maintained. Patients had access to private changing areas, disposable gown and slippers. We observed staff communicating with patients and their families in a respectful and considerate manner.
- Comments documented on patient feedback collated from the provider were positive and included written comments '' staff were so lovely and I really felt taken

care of. Staff were patient and I felt relaxed enough to sit still during the scan' and 'highly recommend as my previous scan had to be cancelled as I couldn't cope in the machine'.

Emotional support

- The service had a 'dignity and respect 'standard operating procedure which stated how patient's privacy and dignity could be maintained.
- Prior to their appointments, patients were provided with an information booklet which explained what an upright scan is, the patient journey and how to get to the clinic. The leaflet also included pictures of people having an upright magnetic resonance imaging scan and a picture from the patient's view.
- During our inspection we observed staff having conversations with patients in areas where they could not be overheard. Patients were given time and privacy to complete the patient questionnaire.
- We observed emotional support being provided by the radiographer, who spoke with patients in a comforting and supportive way. In one case the patient was anxious and the radiographer spoke calmly, explaining all aspects of care and ensured the process wasn't rushed.
- Staff spoke with empathy and genuine warmth about their patients and all strived to ensure the patients' needs were addressed.

Understanding and involvement of patients and those close to them

- Staff told us that no patient would undergo a scan without being fully informed and supported throughout the process.
- During our inspection we observed the radiographer explain to the patient what to expect prior and during the scan along with offering reassurance and ensuring patients were comfortable and didn't feel rushed.
- Patients we spoke with felt fully informed about what to expect prior and during the scan.
- There was no formal chaperone service or guidance for staff to follow and we did not observe any information in any of the areas regarding availability of a chaperone. However, the patient information booklet stated patients could bring someone with them whilst the scan was being performed and staff told us if a patient wanted someone to come in with them, they usually brought someone with them.
- Patients we spoke with told us they felt fully involved with their care and fully informed regarding the scan.

Are diagnostic imaging services responsive?

Good

We have not previously inspected this location. We rated it as good.

Service delivery to meet the needs of local people

- The service offered weight-bearing scans which allowed patient's to be scanned in different positions for example standing upright. The upright scan also offered an alternative option to patients who could not tolerate or cannot be scanned in the conventional way due to obesity, claustrophobia, or conditions which prevented them from lying down for a period.
- The service provided scans to NHS referred patients, independent health care referred patients and self-funded patients.
- Prior to the appointment, patients were sent information including directions and a map to the clinic. Patients also had access to five free parking spaces which were available directly outside the building and the areas were clearly signed.
- The department was clearly signposted and patients were met by the administration staff who showed them to the waiting area. Reception staff told us they would inform patients if there was a delay but this had never happened.
- The appointment time allowed the patient time to complete the safety questionnaire, ask questions and not be rushed. We observed this during our inspection.
- The outpatient department comprised of one reception, one waiting area, two consulting rooms, two changing rooms and one scanning suite. All areas were bright, well furnished, decorated and appropriate for the service.
- In each of the two changing rooms there was a door leading to the corridor which could be locked to prevent access and an additional door which led directly to the scanning suite. Within the changing room was a

wardrobe containing disposable gowns of different sizes and slippers for patients to get changed into prior their scan. In addition, there was a safe where valuables could be securely stored.
- Patients and relatives were provided with disposable earphones to wear whilst in the scanning area. In addition, there was a television screen directly opposite the scanner which the patient could watch with subtitles.

Meeting people's individual needs

- The main entrance to the department was accessed via an intercom and all areas including toilet facilities could be accessed by wheelchair users.
- The patient information leaflet advised patients to notify the service of any additional needs they had. The administration staff told us they usually identified any needs during the phone call to arrange an appointment.
- There was no formal structure to address those patients with additional needs. However, staff told us they responded on an individual basis and recognised when certain patients might require additional support during their scan. Staff gave examples such as patients who were anxious had attended prior to their scan to look around the scanning area and ask questions.
- During our inspection we observed the administrative staff were aware a patient may require assistance due to their mobility and was ready to assist them on arrival.
- In the waiting areas there was a television and reading materials for patients and their family.
- The reception area did not have audio induction loop systems to assist those with hearing difficulties. Staff told us patient information leaflets, safety questionnaires and consent forms were not available in other languages or in other formats for example large print.
- We were told the leaflets were not available in any other format or other languages other than English.
- Translation services were not available for patients whose first language was not English and for patients who required British Sign Language interpreters. Staff gave us an example of a patient who had attended for a scan who spoke very little English and they relied upon the family member to translate what was being said. We were not assured with this process as there is a risk of misinterpretation and /or misleading the patient. We raised this with staff during our inspection and the managing director told us there were no plans for an external interpreter to be available to staff if required one.

Access and flow

- Patients were referred to the service directly from a referring clinician. Self-referral patients were required to have a GP referral and were provided with a referral form for the GP to complete. All scans, once reported, were sent back to the referring clinician with the patient's consent.
- Patients who were referred from a local NHS trust were referred using their own referral form. The scans were sent directly back to the referring clinician who would then report on them.
- Upon receipt of the referral, the administration staff contacted the patient to arrange a convenient appointment and a letter would be sent out to the patient via email or post confirming the date, time and details relating to the scan. Staff told us appointments were usually within seven days.
- Following the scan, patients were provided with a copy scan on a disc and scans were sent via a secure web portal, password protected to the reporting radiologist to be reported on within 48 hours.
- During November 2017 to July 2018 the service had provided upright scans to 154 patients including NHS patients, private health insurance patients and self-paying patients. Data provided showed four children under the age of 18 years had attended during the same period.
- The serviced confirmed during the same period no patients failed to attend their appointments.
- Data provided showed from November 2017 to July 2018, four patients appointments were rearranged due to equipment failure.

Learning from complaints and concerns

- Following their scan, patients were given the opportunity to share information and raise concerns on feedback forms which were then handed to staff. However, there was nowhere on the providers internet site or at the location which gave information to patients as to how they could raise concerns or complain or who to contact.
- The service had a complaints standard operating procedure which stated timelines for a serious or urgent

complaint should be acknowledged immediately along with duty of candour. The procedure stated the patient would then be informed of the outcome within 14 days. However, there was no further information as to how complaints were received, how staff should respond and who is responsible for investigating and responding to complaints.

- Staff told us they would escalate any complaints to their manager, who were based at another location.
- During December 2017 and July 2018, the service received one complaint relating to staff behaviour and it was investigated and actions taken. We did not see evidence that the complaint was acknowledged on receipt or the outcome shared within 14 days but there was reference in a letter sent to the complainant 37 days later that a manager had been in contact with them.

Are diagnostic imaging services well-led?

Requires improvement

We have not previously inspected this location. We rated it as requires improvement.

Leadership

- The service was led by the managing director who was also the registered manager. The management team consisted of the finance director, the radiology manager and the administration manager who were either home based or worked at the London location.
- During our inspection we reviewed staff and reporting radiologist files and observed there was no process in place to ensure checks were completed to evidence if staff were of good character, had the right competencies, skills and were physically and mentally fit for their role. In the four staff files we reviewed we did not see evidence of a disclosure and barring service checks, two had no references and one did not have a health questionnaire.
- We reviewed eight staff files for reporting radiologist and found the tick box checklist inconsistently completed with very little information on. Of the eight checklists we reviewed, none had references, health declaration, evidence of a disclosure and barring check and General Medical Council registration. Two checklists had evidence of qualification and three had indemnity insurance. However, one was recorded as expired in July 2018.
- The managing director told us they would check the medical registration on the internet but would not log the date and findings anywhere.
- At the time of the inspection we escalated our concerns that we were not clear that all relevant checks on employees were performed. We requested evidence be provided that showed how they were assured staff are fit and proper to provide care and treatment. In response the service provided a partially completed checklist which did not have any dates. They also provided a statement that stated that all relevant information for all staff would be checked by 30 September.

Vision and strategy

- Senior managers told us they did not have a written strategy in place as the service had recently commenced. However, they each shared the statement of purpose and vision of the service with us.
- The provider had a statement of purpose with objectives included to achieve a safe, pleasant and caring environment using state-of-the-art equipment, and highly qualified and experienced staff with a focus on diagnostic quality and careful patient handling. The document was not dated, had no version, author or review date and we did not see any evidence within the document of any specific plans in service delivery or timelines.
- During our inspection staff we spoke to were fully aware of the vision of the service and could explain details documented within the statement of purpose.
- We requested a copy of the most recent business plan and were provided with a copy dated 2014. The business plan included a strategy and financial trajectory up to 2016. We were not assured there was a current strategy in place at the time of inspection.

Culture

- Staff felt fully supported by their immediate manager and senior managers. Although the managers weren't based at the location, staff told us they were visible as they visited the department on a regular basis.

- Staff told us they felt valued and were comfortable in raising concerns directly with their line manager and to the registered manager.
- Staff were proud of the department they worked in and providing the service to patients.

Governance

- There was a governance structure. However, the provider could not provide evidence this was effective for example meetings were not minuted and risks were not documented.
- We requested a copy of the board meetings and found these to contain basic information with only the managing director in attendance. We were therefore not assured all issues, risk or performance were actioned or monitored.
- The managing director told us they only attended board meetings and shared the minutes with senior managers.
- All standard operating procedure we reviewed were based on the regulations rather than specific guidelines. This meant they were not always clear as there was duplication of information throughout the procedures. For example, safe, care and treatment procedure included information on preventing abuse and access for wheelchairs at the main entrance.
- The standard operating procedures also did not state training requirements for designated staff and had limited reference to relevant and current national guidance. For example, there was no reference to Gillick competence (used to assess whether children can give consent) in the consent policy and intercollegiate guidance in the safeguarding policy.
- The managing director told us they were in the process of reviewing the standard operating procedures.
- We reviewed pathways and documents. Examples included sequence pathways, patient pathway and the safeguarding policy. These pathways and documents had no headings to state what it was, whether it was devised by the provider, the author, no version control or date of implementation or review. Therefore, we are not assured whether the documents had been ratified, were in current use or whether they were monitored to ensure they reflected current guidance, for example the safeguarding policy.
- Data showed that the provider had no service level agreements in place at the time of inspection. Staff told us the provider had a verbal agreement with a local NHS trust to perform upright scans on patients mostly who were claustrophobic.

Managing risks, issues and performance

- Senior managers told us risk, issues and performance were discussed on a regular, sometimes daily basis, at meetings or via email. However, there was no formal documentation. We are not assured that actions were taken to address or monitor risks, issues or performance in a timely manner or who was the responsible owner.
- We spoke with managers who were aware of the current risks and actions taken to mitigate risk. However, there were no timelines identified.
- We were not provided with any evidence that following the internal clinical audit of radiologists' reports that information was being collated. We were not assured if performance of radiologists was being monitored and areas requiring improvement were being actioned.
- Standard operating procedures stated that environment risk assessments should be completed every three months. The senior manager confirmed the risk assessments hadn't been completed. The provider told us that they would get the administration staff to attend training and complete the risk assessments.
- Following our inspection, we requested a copy of any completed risk assessments including environment, staff and patients. The provider informed us there were none. We are therefore not assured that there was risk oversight or monitoring of risk.

Managing information

- Patients were given a copy of the provider's privacy notice which explained the sharing of patient information with other health care professions. It also explained patients had a choice and who to contact if they wished to discuss this further.
- Each member of staff had a user name and log in to access IT systems and we observed this during our inspection.
- Patient scans were saved and sent via a secure web portal, password protected to the reporting radiologist and we were told data on the server was backed up daily with the data moved to a different location.

Engagement

Requires improvement

Diagnostic imaging

- Senior managers told us they engaged on a regular basis with staff either face to face, via email or phone call. Staff we spoke to confirmed this.
- Staff told us they were informed there were monthly meetings at the London location. However, since the location in Manchester had opened there had only been one meeting. We reviewed the minutes from the meeting and noted managers, radiographers and administrative staff had attended. Policy updates, finances and general data protection regulation was discussed with actions documented against individuals.
- Senior managers confirmed staff meetings had not taken place at the location but felt this wasn't necessary as any information was shared directly with staff. During our inspection staff were aware of recent and ongoing issues relating to the service.
- Following their scan, all patients had the opportunity to provide feedback about the service and their experience via a patient questionnaire. We were told the feedback questionnaires were audited quarterly and staff told us feedback had been positive. However, staff gave us two examples of changes made in response to patient feedback including grab rails on the scanner and larger signage on the outside of the building.
- During our inspection we viewed 103 patient feedback forms and found the responses were rated either good or excellent. For example, 100 patients stated their scan experience overall was excellent and three felt it was good. For the question 'was the safety questionnaire was adequately explained' 99 scored excellent and four scored good. All responses stated they would recommend the service.

Learning, continuous improvement and innovation

- Due to the limited time the service has been operating there is nothing to report within this section.

Outstanding practice and areas for improvement

Areas for improvement

Action the provider MUST take to improve

Action the provider MUST take to meet the regulations:

- The provider must ensure staff have access to policies and procedures that are robust, clear and reflect current guidance to enable them to perform their role.
- The provider must provide staff with training relevant to their role.
- The provider must ensure staff are aware the location of and how to switch the scanner off in an emergency.
- The provider must ensure records are stored securely.
- The provider must ensure risk is assessed and there are processes in place for staff who work alone to follow.
- The provider must have systems in place to demonstrate competence of staff is assessed.
- The provider must ensure information about how to complain or raise concerns is available and accessible to people who use the service.
- The provider must take action to ensure effective systems and processes are in place in assessing, monitoring and mitigating of risk and improving quality and safety of the service.
- The provider must have robust recruitment processes, including undertaking checks, ongoing monitoring to ensure staff employed are 'fit and proper'.

Action the provider SHOULD take to improve

Action the provider SHOULD take to improve

- The provider should make sure any actions taken and lessons learned following incidents are implemented and shared with all staff.
- The provider should ensure that doors to the control are lockable and that staff have access to an alarm within the magnetic resonance imaging to alert other staff if they require urgent assistance.
- The provider should consider devising a policy and providing information to patients regarding access to a chaperone.
- The provider should consider providing staff and patients access to translation services and literature in other formats or languages if they are required.

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 5 HSCA (RA) Regulations 2014 Fit and proper persons: directors Processes must be established to ensure directors of the service is 'fit and proper' to carry out their role and are reviewed on a regular basis. Regulation 5(1)(2)(a)(3)(a)(b)(c)(6)

Regulated activity	Regulation
Diagnostic and screening procedures	Regulation 17 HSCA (RA) Regulations 2014 Good governance Effective systems and processes must be established to ensure compliance with the requirements in this part. Such systems and processes must enable the registered person to assess, monitor and improve the quality and safety of the service and the quality of the experience of service users in receiving the service. Systems or process must be established and operated effectively to enable the registered person, 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 arise from carrying on of the regulated activity. Records should be kept secure at all times and only accessible by authorised people as necessary to deliver peoples care and treatment in a way that meets their needs and keeps them safe. Systems and processes must be established to enable the registered person to evaluate and improve their practice in respect of the processing of information through effective audit and governance systems.

This section is primarily information for the provider

Requirement notices

Regulation 17(1)(2)(a)(b)(c)(f)

Regulated activity	Regulation
Diagnostic and screening procedures	Regulation 18 HSCA (RA) Regulations 2014 Staffing Staff should be supported to make sure they can participate in statutory training, other training, as defined by the provider for their role and other learning and development opportunities required to enable them to fulfil their role. Where appropriate, staff must be supervised until they can demonstrate required/ acceptable levels of competence to carry out their role unsupervised. All learning and development and required training should be monitored and appropriate action taken quickly when training requirements are not being met. Regulation 18 (2)(a)

Regulated activity	Regulation
Diagnostic and screening procedures	Regulation 19 HSCA (RA) Regulations 2014 Fit and proper persons employed Recruitment procedures, systems and processes must be established to ensure persons employed are 'fit and proper' and have appropriate and current registration with an appropriate professional regulator to provide care and treatment appropriate to their role. Systems and processes must be established to ensure there is ongoing monitoring of staff to make sure they remain able to meet the requirements. Regulation 19(1)(a)(b)(2)(a)(b)(4)(a) (5)