Medserena Upright MRI Centre

Quality Report

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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?	Not sufficient evidence to rate
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 Limited. The service provides MRI (Magnetic Resonance Imaging) diagnostic facilities for adults and young people over the age of 12 years.

We inspected magnetic resonance imaging (MRI) diagnostic facilities.

We inspected this service using our comprehensive inspection methodology. We carried out the unannounced inspection on 27 February 2019.

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

Summary of findings

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.

The service provided by this unit was MRI. We have not previously inspected this service.

Services we rate

This was the first inspection of this service. We rated it as **Requires improvement** overall.

- Staff did not follow incident reporting procedures. There had been an incident which staff had responded to, but, managers were unaware of. Staff were aware of the provider's incident reporting procedures, but, did not report or document the incident.
- A stand aid toilet frame in a toilet on the scanning floor was not labelled to indicate if the stand aid frame was MRI safe.
- A patient call alarm in the patient toilet could not be reached by patients using the facilities.
- A first aid box in the kitchen contained a number of out of date dressings. There was no documented review schedule for the first aid box.Resus trolley items were stored randomly and there were items out of date in the resus trolley. Colour coded needle colours were stored in the same compartment in the resus trolley. Two sharps bins in the MRI observation area were open and did not have information recorded, such as the date of opening.
- Electrical safety testing had not been completed to ensure non-clinical electrical equipment was safe to use.
- Contrast was administered at the centre, there were no records of the authorisation process for the administration of contrast.
- There was a lack of effective governance processes to assess, monitor and review risks.
- There were no meetings or formal measures of performance, with the exception of financial performance.
- Managers did not demonstrate a thorough awareness of their regulatory responsibilities.

However, we also found:

- Patients were treated with kindness, dignity and respect.
- Patients received information in a way which they understood and felt involved in their care.
- Staff provided patients and those close to them with emotional support. Staff were supportive of anxious, phobic or distressed patients.
- Staff were positive about their local leaders and felt they were well supported.

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 two requirement notices. Details are at the end of the report.

Nigel Acheson

Deputy Chief inspector of Hospitals (London and the South East)

Summary of findings

Our judgements about each of the main services

Service	Rating	Summary of each main service
Diagnostic imaging	Requires improvement 	Diagnostics was the only activity the service provided. We rated this service as requires improvement because improvements were required for safe and well led.

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

This report relates to magnetic resonance imaging (MRI) services provided by Medserena Upright MRI Centre in London. It is one of two services owned by Medserena Upright MRI Limited (Ltd); the other service is based in Manchester.

The centre provides a wide range of MRI examinations to primarily private fee paying patients. The centre also provides services for some patients referred from the NHS through clinical commissioning groups (CCG) or GPs.

The centre in London first opened in July 2013. The centre provides diagnostic imaging services to adults and young people over 12 years of age.

The service has a registered manager that has been in post since the centre first opened in 2013. The registered manager was registered with the CQC on 12 June 2013.

We inspected the service in London using our new phase inspection methodology. We carried out an unannounced inspection on 27 February 2019.

The centre accepts referrals from both UK and international patients.

Our inspection team

The team that inspected the service comprised a CQC lead inspector and a specialist advisor with expertise in magnetic resonance imaging (MRI).The inspection team was overseen by Terri Salt, Interim Head of Hospital Inspections North London.

Information about Medserena Upright MRI Centre

The provider Medserena Limited is a subsidiary of Medserena AG and was incorporated in England on 31st March 2011, having its registered office at 114a Cromwell Road, London, SW7 4ES. Medserena AG is headquartered in Cologne, Germany.

The Medserena Upright MRI Centre's London site has one upright magnetic resonance imaging (MRI) scanner.

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; the registered manager, the operations manager, clinical lead, administrative manager, and a radiographer. We spoke with four patients.

There were no special reviews or investigations of the unit ongoing by the CQC at any time during the 12 months before this inspection. This was Medserena Upright MRI Centre's, London, first inspection since registration with CQC.

In the reporting period 1 January to 31 December 2018 Medserena Upright MRI Centre provided 1227 attended appointments.

Staff in the unit consisted of a general manager, two radiographers, three administrative staff and two clinical staff.

Track record on safety

- No never events.
- No serious injuries.
- No incidences of healthcare acquired Meticillin-resistant staphylococcus aureus (MRSA).

Summary of this inspection

- No incidences of healthcare acquired Meticillin-sensitive staphylococcus aureus (MSSA).
- No incidences of healthcare acquired Clostridium difficile (c. diff).
- No incidences of healthcare acquired Escherichia coli (E-Coli).
- No deaths.
- No formal complaints.

Services provided under service level agreement:

- Clinical and or non-clinical waste removal
- Building Maintenance
- Laundry
- Maintenance of medical equipment
- Registered medical officer (RMO) provision
- Image reporting
- Mandatory training

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

We rated safe as **Requires improvement** because:

- Although staff had access to a level 4 safeguarding nurse, there was no service level agreement for the provision of level 4 safeguarding support.
- There were no records of cleaning or audits of staff compliance with hand hygiene .
- Some items of equipment were not serviced or tested. Some items of equipment were not stored or labelled in a way that would keep patients safe at all times.
- The service did not follow best practice when prescribing and recording medicines.
- Staff recognised incidents but did not always report them appropriately. There was no formal procedure for sharing learning from incidents with staff.

However, we also found:

- The service provided mandatory training in key skills to all staff and made sure everyone completed it.
- Staff completed and updated risk assessment questionnaires for each patient.
- The service had enough staff with the right qualifications, skills, training and experience to keep people safe from avoidable harm and to provide the right care and treatment.
- Staff kept updated records of patients' care and treatment.

Are services effective?

Not sufficient evidence to rate

We do not currently rate effective for diagnostic imaging.

- The provider could not be assured that staff were fully aware of the requirements of the Mental Capacity Act 2005 and associated guidance.
- The MRI safety committee did not have scheduled meetings to discuss regulations or new guidance.
- Staff worked collaboratively as part of a multi-professional team to meet patients' needs.
- There were systems to show whether staff were competent to undertake their jobs and to develop their skills or to manage under-performance.
- There was effective multidisciplinary team working throughout the unit and with other providers.

Summary of this inspection

Are services caring?

Good

We rated caring as **Good** because:

- Patients were treated with kindness, dignity and respect. This was reflected in feedback we received from patients.
- Patients received information in a way which they understood and felt involved in their care. Patients were always given the opportunity to ask staff questions, and patients felt comfortable doing so.
- Staff provided patients and those close to them with emotional support; staff were supportive of anxious, phobic or distressed patients.

Are services responsive?

Good

We rated responsive as **Good** because:

- Staff were encouraged by the provider to resolve complaints and concerns locally.
- The centre ensured a quick turnaround on the reporting of procedures.
- Patients were offered a range of appointment slots.
- Patients could access services when they needed them. Appointments were flexible and waiting times short. Appointments and procedures occurred on time.

Are services well-led?

Requires improvement

We rated well-led as **Requires improvement** because:

- The provider did not have a clear governance structure. There was limited evidence of information of clinical risks and performance on the agenda at governance meetings.
- A risk assessment had been introduced as a register of risks. However, we found some risks were not identified on the risk assessment. There was no regular review schedule in place for reviewing risks on the risk assessment.
- Team meeting minutes contained limited information in regards to clinical quality assurance and clinical risks.
- The provider could not be assured that the provider could demonstrate an awareness of their regulatory responsibilities.

However, we also found:

- Staff were positive about their local leaders and felt they were well supported.

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	Not rated	Good	Good	Requires improvement	Requires improvement
Overall	Requires improvement	Not rated	Good	Good	Requires improvement	Requires improvement

Requires improvement

Diagnostic imaging

Safe	Requires improvement
Effective	Not sufficient evidence to rate
Caring	Good
Responsive	Good
Well-led	Requires improvement

Are outpatients and diagnostic imaging services safe?

Requires improvement

Mandatory training

The service provided mandatory training in key skills for all staff and made sure everyone completed it.

- Prior to inspection the provider did not submit any data relating to mandatory training modules or compliance.
- Annual mandatory training courses were undertaken. Staff told us mandatory training included 'face to face' and 'e-learning' modules delivered by external providers. Staff training files included a contemporaneous training record. However, the certificates we viewed were for 'All in one day' classroom delivered mandatory training. For example, the radiographer had completed the one day mandatory training on the 19 January 2019 and their certificate recorded that they had completed modules in: Health and safety, information governance, fire safety, equality and diversity, infection control, food hygiene, basic life support (practical adult and paediatric), moving and handling (practical), safeguarding vulnerable children level one and two, safeguarding adults level one and two, complaints handling and conflict management, and lone worker awareness. Staff told us they felt the one day training equipped them with sufficient knowledge for their practice.
- We reviewed five staff personnel files and found all the staff whose files we viewed had up to date mandatory training. Although staff records we viewed were up to date with mandatory training, managers could not be assured they had clear oversight. Managers told us they would have to look in staff personnel files to see what training staff had completed and when mandatory training was due for renewal.

Safeguarding

Although staff had training on how to recognise and report abuse and they knew how to apply it, there was no service level agreement for the provision of level 4 safeguarding support.

- Staff were trained to recognise adults and children at risk and were supported by the centre's safeguarding policy. Staff we spoke with demonstrated that they understood their responsibilities and adhered to the company's safeguarding policies and procedures.
- The operations manager was the lead for adults and children's safeguarding, they were trained to level three.
- All staff had received training in safeguarding children and young people level two, as it was possible children would be scanned. This met intercollegiate guidance: 'Safeguarding Children and Young People: Roles and competencies for Health Care Staff', January 2019. Guidance states all non-clinical and clinical staff that have any contact with children, young people,

parents or carers should be trained to level two safeguarding. The operations manager had completed level three safeguarding children's training. Managers told us they had access to level four children's safeguarding support from an external provider. However, there was no service level agreement for the provision of this support.

- We reviewed the provider's standard operating procedure (SOP), 'Regulation 13: Safeguarding service users from abuse and improper treatment' did not provide staff with guidance on the Department of Health (DoH) female genital mutilation and safeguarding guidance for professionals March 2016, human trafficking or 'Prevent' counter terrorism. Although, there was a link in the document to the local authority safeguarding children's webpage where information could be accessed including child sexual exploitation (CSE). The webpage also provided advice and a link where the public could contact the local authority safeguarding team.
- Staff told us if they were concerned about any patients they would refer their concerns to the local authority safeguarding team. However, we did not see contact numbers for local adult and child safeguarding teams displayed in the centre. Staff would have to get these details from the safeguarding policy on the company's shared drive. Following our inspection the centre informed us a notice entitled 'Managing Safeguarding Concerns-Medserena London' was displayed on the centre's kitchen noticeboard and this contained contact information for local adult and child safeguarding teams.

Cleanliness, infection control and hygiene

There were no records of cleaning or audits of staff compliance with hand hygiene to provide evidence of the centre's control of infection risks.

- The operations manager was the centre's infection prevention and control lead. This meant there was a named, accountable person to support staff.
- During this inspection we saw all areas of the service were visibly clean. All the patients we spoke with were positive about the cleanliness of the unit and the actions of the staff with regards to infection prevention and control.
- Staff told us an external cleaning company contracted by the landlord cleaned the scanning room at the end of each day, but this was not recorded. Staff told us the operations manager did visual checks on the cleanliness of the centre every morning to ensure the centre was clean, but these were not recorded. This meant the provider could not be assured that all cleaning tasks had taken place on specific days.
- Staff told us they followed manufacturers' instructions for routine disinfection of the MRI scanner. This included the cleaning of medical devices, including the MRI scanner, between each patient and at the end of each day. We saw staff cleaning equipment and machines following each use. However, this was not recorded. Staff told us the provider did not have policy or procedure for the disinfection of the MRI scanner.
- Between January 2018 and January 2019 there had been no incidences of acquired infection in the unit.
- We observed staff demonstrating compliance with hand hygiene technique in washing their hands and using hand gel when appropriate. However, staff told us they did not complete hand hygiene audits. This meant the provider could not be assured of all staff complying with hand hygiene technique at all times. We saw guidance displayed on hand hygiene based upon the World Health Organisation's (WHO) '5 Moments for Hand Hygiene.' These guidelines are for all staff working in healthcare environments and define the key moments when staff should be performing hand hygiene to reduce risk of cross contamination between patients.
- Staff were bare below the elbow and had access to a supply of personal protective equipment (PPE), including gloves and aprons. We saw staff using PPE appropriately.
- We witnessed staff adherence to the National Institute for Health and Care Excellence (NICE) QS61 Statement 5, (People who need a vascular access device have their risk of infection minimised by the completion of specified procedures necessary for the safe insertion and maintenance of the device and its removal). The clinical lead was a registered medical officer (RMO) and would be on site at the unit for any invasive

procedures, staff told us vascular access devices would be disposed of correctly in a contaminated sharps container. We saw containers were available for the disposal of sharps.

- Clinical and general waste was handled and disposed of in a way that kept people safe. Waste was labelled appropriately and staff followed correct procedures to handle and sort different types of waste.

Environment and equipment

The service had suitable premises and equipment. However, some items of equipment were not serviced or tested. Some items of equipment were not stored or labelled in a way that would keep patients safe at all times.

- The layout of the centre was compatible with the Department of Health (DoH) health building notification (HBN06) guidance. Access was via Cromwell Road in Kensington, London. The clinic was in the basement of the building and was accessible by a lift from the ground floor and stairs. The building had a ground floor reception area with a reception desk that was staffed during opening hours by staff employed by the landlord. Medserena Upright MRI Centre had its own reception area in the basement. There was a waiting area in Medserena Upright MRI Centre that provided a range of magazines, refreshments and toilet facilities for patients and relatives.
- The scanning area was located on a mezzanine level in the basement. This was accessible by a chair lift or stairs. The scanning area had a scanning observation area that ensured patients were visible to staff during scanning.
- The mezzanine scanning level had a patient toilet with facilities for patients with a physical disability. However, we found a patient emergency call alarm in the accessible toilet was on a wall next to the door. The alarm was opposite the toilet and could not be reached from a sitting position on the toilet. There was a risk that patients that had problems with transferring from sitting to standing may not be able to reach the call alarm.
- The fringe fields around the MRI scanner were clearly displayed. Fringe field refers to the peripheral magnetic field outside of the magnet core. This reduces the risk of magnetic interference with nearby electronic devices, such as pacemakers. Although the strength of the magnetic fields decreases with distance from the core of the magnet, the effect of the "fringe" of the magnetic field can still be relevant and have influence on external devices.
- The MRI magnet was fitted with emergency "off" switches, which suspended scanning and switched off power to the magnet sub-system. Staff we asked were aware of actions required to stop or suspend scanning in the event of an emergency situation.
- The MRI scanner was equipped with 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 saw records confirming the radiographer performed a phantom scanner check daily prior to patients arriving for appointments.
- An MRI safe wheelchair and trolley were available for patients in the event that they would need to be transferred from the scanner in an emergency.
- There were systems in place to ensure repairs to machines or equipment, when required, were timely. These ensured patients would not experience prolonged delays to their care and treatment due to equipment being broken and out of use. Servicing and maintenance of premises and equipment was carried out using a planned preventative maintenance programme.
- During our inspection we checked the service dates for equipment, including scanners. We found the equipment we checked was within the service date. However, a set of scales for weighing patients did not have a date of servicing or date when servicing was due.
- Failures in equipment and medical devices were reported through the provider's technical support team. Staff told us there were usually no problems or delays in getting equipment repaired.
- Non-medical electrical equipment was not electrical safety tested. Managers told us the centre was in the

process of arranging for the engineer to complete a course in electrical safety testing. However, a training date had not been confirmed at the time of inspection.

- We checked the resuscitation equipment on the MRI unit. The resuscitation equipment appeared visibly clean. Records indicated resuscitation equipment had been checked daily by staff. However, we found some items were out of date in the trolley. We also found colour coded needles were stored in the same compartment in the trolley. This created a risk of staff inadvertently using the incorrect needle for a procedure.
- All MRI equipment was labelled in accordance with recommendations from the Medicines and Healthcare products Regulatory Agency (MHRA). For example, 'MR Safe', 'MR Conditional', 'MR Unsafe'. All equipment in the assessment area was labelled MR unsafe. However, we found a wheelchair that was not marked as 'MR unsafe'. Staff demonstrated how the wheelchair was only used to transport patients to a stair lift which transported patients up four stairs to the scanning area. Staff told us all staff knew the wheelchair should not be taken up the stairs to the scanning area. We also found a stand aid toilet frame on the same floor as the scanning area which was not marked as 'MR unsafe.' Staff told us they were aware that the frame should not be taken into the scanning area. However, it would be safe practice to mark all equipment that was not 'MR safe' to ensure all equipment was clearly identified.
- Access to the MRI room was via a controlled door. There was signage on all doors explaining the magnet strength and safety rules.
- Staff had sufficient space to move around the scanner and for scans to be carried out safely. During scanning all patients were visible to staff and had access to an emergency call/panic alarm. Patients could have music or television programmes of their choice played whilst being scanned. Patients did not require ear plugs or defenders as the upright MRI system did not generate the levels of noise a conventional MRI scanner would generate. There was a microphone that allowed contact between the radiographer and the patient at all times.

Assessing and responding to patient risk

Staff completed and updated risk assessment questionnaires for each patient.

- Staff assessed patient risk and developed risk management plans in accordance with national guidance. For example, the unit used a magnetic resonance imaging patient safety questionnaire.
- Patients had the choice of wearing their own clothes or changing into a gown prior to the scan. This was due to magnetic fields used by MRI are very strong, and metallic items on patients clothes carry accident risks. Most of the patients we saw during the inspection changed into a gown. All patients told us they were given information, were risk assessed and had signed a form to accept they had understood the risks in regards to their choice of clothing and MRI scanning.
- There was a standard operating procedure (SOP) for staff to assess people using services that were clinically unwell and needed to be admitted to hospital. The SOP gave instructions to staff on commencing resuscitation in the event of a medical emergency or cardiac arrest. This was to commence (CPR) and dial 999. The SOP was reviewed and updated in October 2018 and had a next review date of October 2019. Staff we spoke with were aware of the SOP.
- There were procedures for removal of a collapsed patient from the MRI scanner. Staff told us they had evacuated a patient from the MRI safely and it had gone smoothly. However, there was no schedule of skills or drills training for the evacuation of a patient from the MRI scanner.
- The service ensured that the 'requesting' of an MRI was only made by staff in accordance with the MHRA guidelines. All referral forms included patient identification, contact details, clinical history and the type of examination requested, as well as details of the referring clinician/ practitioner.
- Signs were located in the scanning area highlighting the contra-indications to MRI including patients with heart pacemakers, patients .
- In accordance with NICE acute kidney injury (AKI) guidelines and the Royal College of Radiologists

standards for intravascular contrast agent administration, all high risk patients referred for MRI were blood tested for kidney function prior to scanning. This was to reduce the risk of contrast induced nephropathy (CIN)..

- The centre had a standard operating procedure (SOP) for urgent or unexpected clinical findings. Staff we spoke with explained the processes to escalate unexpected or significant findings both at the time of the examination and upon reporting.
- If radiographers thought a patient needed medical attention, the patient was advised to attend their local accident and emergency department or consult with their GP.
- All images could be sent to referrers urgently via the image exchange portal.
- Medical emergency procedures were not regularly audited. This meant the provider could not be assured of staff awareness of the unit's standard operating procedure (SOP) for resuscitation, medical emergency and cardiac arrest.
- There were processes to ensure the correct person got the correct radiological scan at the right time. The centre had a Society and College of Radiographers (SoR) poster within the unit. The posters acted as an aide memoire for staff reminding them to carry out checks on patients.
- We saw staff using the SoR "pause and check" system. Pause and check consisted of a system of demographic checks to correctly identify the patient, as well as checking with the site or side of the patient's body that was to have images taken and the existence of any previous imaging the patient had received. This enabled the MRI operator in ensuring that the correct imaging modality was used, and the correct patient and correct part of the body was scanned.
- Intravascular (IV) contrast administration was carried out at the unit. We saw that protocols were in place including having the clinical lead, who was a registered medical officer (RMO), on-site to treat any severe contrast reactions patients may have during scanning, including anaphylaxis.
- All clinical staff were basic life support (BLS) and automated external defibrillator (AED) trained.
- The administration manager had completed a course in first aid. However, there were no other staff qualified in first aid in the event of the administration manager being on leave.
- Staff had not completed any training in sepsis awareness. Staff said as Medserena Upright MRI Centre was not an acute service it was unlikely that a patient would present with sepsis symptoms. However, if a patient appeared acutely unwell staff would provide first aid and call 999 emergency services.

Staffing

The service had enough staff with the right qualifications, skills, training and experience to keep people safe from avoidable harm and to provide the right care and treatment.

- Required staffing levels were calculated using core service information including: operational hours, patient complexity and service specifications, physical layout and design of the facility/service, expected activities, training requirements, and administrative staffing requirements. This ensured sufficient staff to support patients' needs.
- Staff in the unit consisted of a general manager, two radiographers, three administrative staff and two clinical staff.
- There was a business continuity plan to guide the service when responding to changing circumstances. For example sickness, absenteeism and workforce changes. Agency staff were not used at Medserena Upright MRI Centre in London. Shifts were usually covered by the unit's own staff. This ensured staff continuity and familiarity with the unit.
- All staff we spoke with felt that staffing was managed appropriately.
- Radiologists were provided by a service level agreement (SLA) with an external provider. Radiographers told us they could contact a radiologist at the external provider for advice at any time.
- The clinical lead was the RMO and was employed to support the unit's radiographer in the administration of contrast. The service had a contract with an external RMO service provider to provide medical cover when the clinical lead was on leave or to cover sickness.

- The unit had a contract for an external agency to provide reports written by a reporting radiologist.

Records

Staff kept updated records of patients' care and treatment.

- Staff kept and updated individual patient care records in a way that protected patients' confidentiality. Patient care records were paper based and were accessible to staff.
- Patients completed a MRI safety consent checklist form consisting of the patients' answers to safety screening questions and also recorded the patients' consent to care and treatment. This was filed in patients individual patient records.
- Staff completing the scan, updated the electronic records and submitted the scan images for reporting by a radiologist. The service had a service level agreement with an external private provider for diagnostic image reporting, this included quality assurance agreements in regards to the auditing of reports to review the quality of images provided, clinical errors in the report, and a review of the quality of the transcribed report.
- We reviewed five patient records during this inspection and saw records were accurate, complete, legible and up to date.
- The service provided electronic access to diagnostic results and could share information electronically with referrers.
- The radiology information system (RIS) and picture archiving and communication system (PACS) were secure and password protected, and each member of the clinical staff had their own personal password.

Medicines

The service did not follow legislation when prescribing, administering and recording medicines.

- Staff were trained on the safe administration of contrast media including intravenous contrast. . We observed three patients during our inspection; all patient allergies were documented and checked on arrival in the unit. Staff told us contrast was only administered to patients over 16 years of age.
- Patient specific directions and patient group directions (PGDs) were not used for administration of contrast media. PGDs allow some registered health professionals, such as radiographers, to administer specified medicines to a predetermined group of patients without them seeing a doctor. This was not in accordance with guidance on 'Prescribing' and guidance on the use of 'Contrast agents and other drugs,' from the Society and College of Radiographers (SOR).
- Guidance from the Society and College of Radiographers (SOR), 'Contrast agents and other drugs,' states "Contrast agent injections should only be undertaken if clinically indicated and at the request of the supervising MRI radiologist or radiographer who is appropriately trained and is authorised by the Clinical Director or Lead Radiologist. This authorisation should be documented in the local rules." In response to our concerns the clinical director introduced a prescribing document with immediate effect.
- Patients were not provided with information post scan documenting that they had received contrast. Although patients we spoke with told us they had been advised to seek advice from their GP if feeling unwell after leaving the centre. Referring clinicians would receive patient scan reports.
- The centre did not have an on-site pharmacist. Staff told us they could contact a pharmacist if they had any concerns in regards to medicines patients were taking.

Incidents

Staff recognised incidents but did not always report them appropriately. There was no formal procedure for sharing learning from incidents with staff.

- The service had a standard operating procedure (SOP). 'Regulation 16: Receiving and acting on complaints'. This provided guidance for staff in regards to the process of reporting incidents. However, it was not clear to staff searching for an incident policy that the SOP related to incident reporting, or the relevant regulation, as the SOP title indicated that it related to complaints. The SOP had an accident/incident reporting form as an appendix.

Requires improvement

Diagnostic imaging

- Staff understood their responsibilities to raise concerns, to record safety incidents, and investigate and record near misses. Managers told us there had been no incidents in the service. However, one member of staff told us there had been an incident involving a patient that became unwell in the scanner. When we raised this with managers they told us they were unaware of the incident. The incident had not been recorded. This meant the service could not be assured that staff were implementing the provider's incident reporting procedures.
- There was no formal procedure for sharing learning from incidents with staff. Staff told us there were very few incidents at the centre due to the service being relatively small and patients being offered a minimum appointment of one hour. Managers also said the team were a small team and would communicate with each other daily. However, this was not a robust method of managing incidents. There was no formal process for the analysis of incidents and identification of themes and shared learning to prevent reoccurrence at a local and organisational level. At the time of the inspection managers told us they would introduce a formal agenda for staff meetings with immediate effect which included incident reporting to prompt staff to report any incidents.
- During the period February 2018 to February 2019 there had been no serious incidents requiring investigation, as defined by the NHS Commission Board Serious Incident Framework 2013. Serious incidents are events in health care where the potential for learning is so great, or the consequences to patients, families and carers, staff or organisations are so significant, that they warrant using additional resources to mount a comprehensive investigation. Managers also said there had been no serious incidents since the centre opened in 2013.
- There had been no 'never events' in the previous 12 months prior to this inspection. Never events are serious incidents that are entirely preventable as guidance, or safety recommendations providing strong systemic protective barriers, are available at a national level, and should have been implemented by all healthcare providers.
- There had been no notifiable safety incidents that met the requirements of the duty of candour regulation in the 12 months preceding this inspection. 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) of certain notifiable safety incidents and provide reasonable support to that person.
- The provider's 'Regulation 16: Receiving and acting on complaints,' SOP prompted staff to give consideration to the duty of candour in the event of a serious incident meeting the duty of candour requirements. Furthermore, there was a 'Regulation 20: Duty of Candour' SOP to guide staff in the steps to take in the event of an incident meeting these requirements.
- Staff we asked demonstrated that they understood the requirements of the duty of candour regulation. The SOP outlined how incidents involving patient or service user harm would be assessed with the 'notifiable safety incident' criteria as defined within regulation 20 of the Health and Social Care Act 2008 (regulated activities) Regulations 2014. Incidents meeting this threshold would be managed under the providers 'Regulation 20: Duty of Candour' SOP for the notification of a notifiable safety incident.
- We asked the provider how National Patient Safety Alerts (NPSA) that were relevant to the centre would be communicated to all staff. The provider informed us that as the service was not an NHS service they did not receive patient safety alerts. Patient safety alerts are issued via the Central Alerting System (CAS), this a web-based cascading system for issuing alerts, important public health messages and other safety critical information and guidance to the NHS and other organisations, including independent providers of health and social care. This meant the provider was not receiving information which could be used to develop guidance to protect patients from harm.

Are outpatients and diagnostic imaging services effective?

Not sufficient evidence to rate

This was the first inspection for this service. We do not currently rate effective for diagnostic imaging.

Evidence-based care and treatment

Requires improvement

Diagnostic imaging

The service could not be assured it provided care and treatment based on national guidance as there was a lack of systems to monitor evidence of its effectiveness.

- We asked staff about local rules. Staff told us the centre did not have local rules although there was guidance for staff on operating the MRI. Safety guidelines from the Medicines and Healthcare products Agency (MHRA), 2015, recommend that the MR responsible person ensures that adequate written safety procedures, work instructions, emergency procedures and operating instructions, are issued to all concerned after full consultation with the MR safety expert and representatives of all MR authorised personnel who have access to the equipment (see section 4.7). Local rules should be reviewed and updated at regular intervals and after any significant changes to equipment." Managers told us they did not know what local rules were.
- Following our inspection we requested the centre's local rules. In response the provider sent us the centre's MRI safety rules, dated June 2013 and updated in March 2019. The MRI safety rules were generic to MRI scanners and were not localised to the scanner in-situ in the centre. For example, there was a diagram showing the fringe fields of the MRI scanner, but, the diagram did not demonstrate the fringe fields in the actual scanning room in the centre. The safety rules did not have a record of previous reviews prior to March 2019, although there was next review date recorded as March 2020. The safety rules had Medicines and Healthcare products Regulatory Agency (MHRA) guidelines attached, but the centre had not adopted some of the recommendations, such as a regular health and safety committee meeting.
- Following our inspection the provider informed us that it was the responsibility of the Medserena MRI safety committee to ensure that the MRI safety guidelines were established and maintained. The provider informed us that procedures were in place to ensure that all adverse MRI safety events were reported to the chair of the MRI safety committee; this was the medical physics expert in Cologne, Germany, within a 24-hour period. The Medserena MRI safety committee would only be convened in the case of a serious adverse event. The provider added that in the course of five years no such incidents had been reported. However, there had been no meetings of the safety committee to review regulations and new safety guidance.
- Patients care and treatment was delivered in accordance with guidance from the National Institute for Health and Care Excellence (NICE). NICE guidance was followed for diagnostic imaging pathways as part of specific clinical conditions. However, there was no evidence of monitoring of patient outcomes, with the exception of patient reported satisfaction feedback.
- Staff assessed patients' needs and planned and delivered patient care in line with evidence-based, guidance, standards and best practice. For example, staff followed the MHRA guidelines safety guidelines for magnetic resonance imaging equipment in clinical use. However, there was no annual audit to assess that clinical practice was in accordance with local and national guidance.

Nutrition and hydration

- Patients had access to water and hot drinks whilst awaiting their scan. During our inspection we observed staff offering patients drinks before and after they were scanned.

Pain relief

- Pain assessments were not undertaken at the location. Patients managed their own pain and were responsible for supplying any required analgesia. We were shown a letter patients received prior to the procedure advising them to continue with their usual medications.
- We saw staff asking patients if they were comfortable during our inspection. Staff also asked patients to identify areas where they experienced pain during their scans. This enabled staff to scan areas where patients reported that they suffered pain.

Patient outcomes

Managers did not monitor the effectiveness of care and treatment and use the findings to improve them; or compare local results with those of other services to learn from them.

Diagnostic imaging

- Staff informed us that patient reported satisfaction questionnaires were the main method of monitoring patient outcomes. All patients were asked to complete a satisfaction survey following treatment at the clinic. Patients' comments were monitored by the administration manager. But there was no system of monitoring results to identify themes and trends. Staff told us 80% of patients completed a patient satisfaction survey following their scan. We reviewed 10 patient satisfaction surveys and found all patient responses were positive about their experience at the centre.
- Audits of the quality of the images were not undertaken at a local or corporate level to highlight any deficiencies in images for staff learning. Staff told us referrers were telephoned to ensure they were satisfied with the service, but this was not recorded. However, following our inspection the provider informed us the clinical lead continuously reviewed patient images and provided feedback to the radiographer regarding the quality of the images and any changes, adjustments or improvements that need to be made. The provider informed us that this was a real-time ongoing process and did not need an audit process. However, there were no records of feedback the clinical lead had provided to the radiographer submitted to the CQC.
- Clinical audits were completed by an external reporting radiologist. These audit results were sent for review and comment by the provider. We viewed three clinical audits for October, November and December 2018. These audits included a review of 21 patient reports. The audits used a red, amber, green (RAG) system to highlight the quality of images in individual report audits. We found all the audit reports we viewed had received a green rating. However, there were two audit reports in the period where there had been issues, the reports identified that the discrepancy related to wording of the reports and not the quality of images. Actions were identified on the reports for the external radiologist to clarify the wording of the report. Following our inspection the centre informed us where reports were red or amber rated the clinical director would address this with the reporting radiologist.
- Patients did not have review appointments scheduled following treatment to discuss their progress and satisfaction following scans. Following our inspection the centre informed us that MRI scanning services were provided by referral from patients GP or consultant referrers. If patients required further investigations or scans following their initial visit, this would be requested as a separate referral by the GP or consultant.
- There had been no deaths of patients resulting from procedures in the previous 12 months.
- Staff told us there had been no incidents of patients having adverse reactions or side effects to treatment. In the event of a patient experiencing side effects to treatment this would be monitored by the centre's incident reporting system.

Competent staff

The service made sure staff were competent for their roles.

- All staff received a local induction and underwent an initial competency assessment. We requested from the service the percentage of staff that had completed and induction. However, we received a copy of a blank induction and competency assessment for radiography staff in response.
- Staff we spoke with told us they had received a local induction. This ensured staff were competent to perform their required role. For radiographers, this was supported by a competency assessment which covered the key areas applicable including equipment, and clinical competency skills relevant to their role. The competency assessment for radiography staff was signed and dated by the operations manager to indicate the radiographer was competent in specific tasks and the use of equipment.
- Administrative staff received an induction to the MRI scanner, as well as administrative systems, such as the bookings system, invoicing and provider specific electronic systems, such as the providers shared drive on the computer.
- All staff had received an annual appraisal in the previous 12 months.

- Staff had the right skills and training to undertake the MRI scans. The radiographer and operations manager were required to complete the Medserena mandatory training programme as well as role specific training to support ongoing competency with MRI equipment. We viewed a radiographer's continuous professional development (CPD) records and found these included a competency assessment, self-directed learning, and skills training.
- Managers told us the clinical lead had vast clinical experience and the radiographer also had a number of years MRI experience.
- Staff we spoke with told us the provider had an internal training programme for magnetic resonance imaging (MRI) aimed at developing upright MRI specific competence.
- Staff had the opportunity to attend relevant courses to enhance the professional development and this was supported by the company and local managers. Medserena offered access to both internal and externally funded training programmes to support staff in developing skills and competencies relevant to their career. For example, the operations manager told us the provider had supported them in studying for a Master's degree.
- Radiographers' performance was monitored by the operations manager and issues were discussed in a supportive environment. Radiologists fed back any performance issues with scanning to enhance learning or highlight areas of improvement in the radiographers' performance.
- All radiography staff were registered with the Health and Care Professions Council (HCPC) and met HCPC regulatory standards to ensure the delivery of safe and effective services to patients.

Multidisciplinary working

Staff of different kinds worked together as a team to benefit patients.

- Staff told us the service had good relationships with external partners and undertook scans for NHS providers, foreign embassies' and providers of private healthcare insurance.
- Staff told us there was good communication between services and there were opportunities for them to contact referrers for advice, support and clarification.
- The clinical lead attended a bi-monthly meeting with other private health care providers of neurosurgery and hypermobility to discuss Ehlders-Danlos syndromes (EDS). EDS are a group of rare inherited conditions that affect connective tissue that provide support in skin, tendons, ligaments, blood vessels, internal organs and bones.

Seven-day services

- The unit was operational from 8am to 5.30pm Monday to Friday.
- Appointments were flexible to meet the needs of patients, and appointments were available at short notice.

Health promotion

- Information leaflets were provided to patients prior to their scan and in the centre on what the scan would entail and what was expected of them prior to a scan. The unit also provided information to patients on self-care following a scan.
- The centre's website provided a wide range of information and access to wide range information on MRI scanning, including information on medical conditions that may benefit from and upright MRI scan.

Consent and Mental Capacity Act

The provider could not be assured staff understood their roles and responsibilities under the Mental Capacity Act 2005.

- Staff we spoke with had some knowledge of the requirements of the Mental Capacity Act 2005 (MCA). We asked the general manager and operations manager about staff training. The registered manager showed us evidence that the radiographer had completed training in the Mental Capacity Act 2005 in August 2016. Staff had not received any further training updates, although staff had access to guidance on the act.
- We subsequently viewed the centre's standard operating procedure (SOP), 'Regulation 12: Safe care

and treatment' and found the Mental Capacity Act 2005 was not listed in the documents reference list. We found a link in the document to the act was recorded in the SOP twice as a link to the Mental Health Act; this is different legislation from the Mental Capacity Act 2005. Furthermore, a link in the provider's standard operating procedure (SOP) document, 'Regulation 13: Safeguarding service users from abuse and improper treatment' to the Mental Capacity Act toolkit, did not work when we attempted to access this. This did not assure us in regards to staff having knowledge of and access to guidelines on the Mental Capacity Act 2005.

- During this inspection there were no patients that lacked the capacity to make decisions in relation to consenting to their scan. Staff also told us they would encourage patients to be accompanied where there were concerns about their capacity to consent. Staff told us they would not make an appointment for a patient where there were doubts about the patient's capacity to understand their care and treatment.
- Staff we spoke with were aware of the need for consent and gave patients the option of withdrawing consent and stopping their scan at any time. The service used a MRI consent form to record patients' consent which also contained the patients' answers to their safety screening questions.
- Staff were aware of children's consent procedures. Young people (aged 16 or 17) were presumed to have sufficient capacity to decide on their own medical treatment, and provide consent to treatment, unless there was significant evidence to suggest otherwise. Staff we spoke with were able to tell us about Gillick competence. This is a term used in medical law to decide whether a child (under 16 years of age) is able to consent to his or her own medical treatment, without the need for parental permission or knowledge.

Are outpatients and diagnostic imaging services caring?

Good

This was the first inspection for this service. We rated caring as **good.**

Compassionate care

Staff cared for patients with compassion. Feedback from patients confirmed that staff treated them well and with kindness.

- During this inspection we saw all staff treated patients with dignity, kindness, compassion, courtesy and respect. Staff demonstrated a kind and caring attitude to patients. Staff introduced themselves and explained their role. Staff interacted well with patients and included patients in general conversation. Feedback provided by patients further demonstrated patients felt staff had treated them with courtesy, kindness and respect.
- Staff ensured that patients' privacy and dignity was maintained during their time in the unit and during MRI scanning. Patients changed clothing and waited in changing rooms which led directly to the scanning areas. Patients were provided with a dressing gown in the changing room to protect their modesty whilst waiting in the changing rooms and during their time in the scanning area.
- Patient satisfaction was measured through completion of the patient satisfaction survey following their examination. We viewed 10 patient satisfaction surveys dated February 2019 and found all patient feedback was very positive about the care and treatment they had received. The administration manager told us they monitored patient feedback and used positive comments to praise the staff or in the case of negative comments the administration manager would investigate and use the patients' comments to improve the service.
- During this inspection we spoke with four patients about various aspects of the care they received. Without exception, feedback was positive about staff and the care they delivered.

Requires improvement

Diagnostic imaging

Emotional support

Staff provided emotional support to patients to minimise their distress.

- Staff supported people through their scans, ensuring they were well informed and knew what to expect. Patients were actively invited to visit the centre prior to their scan to allay any anxieties they may have about the scanning procedure.
- Staff provided reassurance and support for nervous, anxious, and claustrophobic patients. They demonstrated a calm and reassuring attitude so as not to increase patients' anxiety.
- Staff provided reassurance throughout the scanning process, they updated the patient on the progress of the scan and how long they had before their treatment was complete. All the patients we spoke with told us staff had been supportive. For example, a patient told us, "The radiographer was brilliant. They were very natural and very supportive."
- The centre's staff we spoke with felt that recognising and providing emotional support to patients was an integral part of the work they did. The service specialised in providing scanning to anxious and phobic patients. Staff recognised that scan-related anxiety could impact on a patient's scan and this could result in possible delays with the patient's treatment. The centre had an up to date chaperone policy. Patients were asked at the time of booking if a chaperone was required.

Understanding and involvement of patients and those close to them

Staff involved patients and those close to them in decisions about their care and treatment.

- Staff communicated with patients in a manner that would ensure they understood the reasons for attending the unit. All patients were welcomed into the reception area and reassured about their procedure. For example, a patient told us, "They explained everything; they told me how long each scan would take. I felt informed and involved throughout the process."
- Staff recognised when patients or relatives and carers needed additional support to help them understand and be involved in their care and treatment. Staff enabled them to access this, including access to interpreting and translation services.
- Patients and relatives and carers could ask questions about their scan. Patients could access information on upright MRI scanning from the company's website. However, there was a limited range of information available to patients in the centre.
- The service allowed for a parent or family member or carer to remain with the patient for their scan if this was necessary.
- Patients were provided with an information leaflet when they received confirmation of their appointment. This explained the differences between upright and conventional MRI scanning. Staff also gave patients information on preparing for a scan and what they should bring with them to their scan, including referral letters and medical insurance details if applicable. The leaflet also advised patients on what to wear to their scan, for example, patients should not wear clothing with metal fasteners or under wiring. The leaflet also informed patients of contra-indications and that these should be discussed with staff prior to an appointment, including tattoos and piercings.

Are outpatients and diagnostic imaging services responsive?

Good

This was the first inspection for this service. We rated it as **good.**

Service delivery to meet the needs of local people

The service planned and provided services in a way that met the needs of patients.

- The Medserena Upright MRI Centre in London opened in 2013. The centre's focus was on the provision of upright magnetic resonance imaging (MRI) scanning

and reporting services. Patients consisted of a mix of private self-pay patients, patients funded by private health insurance, patients referred by overseas Embassies, and NHS patients.

- The site had one upright magnetic resonance imaging (MRI) scanner, two non-clinical meeting rooms, a reception area and patient waiting area. There was also a staff kitchen.
- The environment was patient centred. Medserena Upright MRI Centre was located in a modern building. The unit had comfortable and sufficient seating in reception areas. Toilets and drinks were available to patients and visitors in the main reception waiting area.
- The upright MRI scanner offered weight-bearing scans with the patient sitting or standing. The design of the upright scanner allowed patients to be positioned in different postures from conventional MRI scanners, and meant different.
- The centre specialised in offering upright MRI scanning for claustrophobic or anxious patients who could not tolerate a conventional, "tube or bore", MRI examination. This included patients with severe curvature of the spine patients with emphysema, and obese patients who could not use a conventional MRI scanner. The upright scanner could also be used for patients with anxiety or claustrophobia as the scanner was open at the front, patients could see outside the scanner and could see the centre's staff and friends or relatives.
- A calendar was used to monitor the centre's capacity and allowed administrators to monitor the availability of appointment slots. All appointments were a minimum of 45 minutes with most appointments being for a one hour slot.
- The centre was located on Cromwell Road in London. The unit was accessible by public transport being three minutes' walk from Gloucester Road underground station or a two minute walk from bus stops on Cromwell Road. The centre was open Monday to Friday.
- Most patients, 99%, were either private fee paying patients or patients with medical insurance. Managers told us NHS patients made up 1% of referrals to the centre. Managers told us the service had service level agreements with two NHS trusts, but had not received any patient referrals as a result of these agreements. All the NHS patients the centre had treated had been individually funded patients from either an NHS hospital trust or their local clinical commissioning group.
- When contrast enhanced MRI scans were provided the clinical lead was always on site to oversee the procedure and to support staff if they needed medical advice about escalation or in the event of a medical emergency. The centre had a booking process to ensure a registered medical officer was on-site before the procedure commenced. Radiographers did not commence contrast scanning without the presence of the clinical lead. The availability of the clinical lead and appointments was managed by the administration manager.

Meeting people's individual needs

The service took account of patients' individual needs.

- Staff had an understanding of the cultural, social and religious needs of patients. For example, staff told us they provided services for Embassies and patients from overseas and appointments were reduced on a Friday to respect the Jewish Sabbath. A patient safety questionnaire was available in Arabic.
- The clinical lead specialised in Ehlers-Danlos syndromes (EDS), these are a group of rare inherited conditions that affect connective tissue. The provider was the only provider of cranial instability EDS MRI scanning in Europe. These scans were only provided on days when the clinical lead was on-site.
- Staff could use a telephone interpreting service for patients that did not speak English. Patients were advised on the availability of interpreters at the point of booking. Interpreters would be booked by the administration manager for the time of the patient's appointment.
- Nervous, anxious or phobic patients could have a preliminary look around the unit prior to their appointments to familiarise themselves with the

environment and decrease anxiety. A patient we spoke with told us they had a preliminary visit to the centre prior to their scan and this had helped to alleviate their anxiety about having a scan.

- Patients with a learning disability or dementia could bring a relative or carer to their appointment as support. Patients and relatives could be present in the scanning room if required.
- Microphones were built into the scanner to enable two-way communication between the patient and staff.
- Staff told us patients could bring their own music for relaxation. Patients we asked told us that they could have their own music, and they were also offered a choice of radio and television stations during their scan.
- Patients were advised that if they wanted to stop their scan, staff would assist them and discuss choices for further imaging or different techniques or coping mechanisms to complete their imaging.
- Patients with mobility needs had access to a lift to gain access to the basement of the building where the centre was located. There was also a stair lift to take people to the scanning floor.
- An MRI compatible wheelchair was available for patients that were unable to weight bear.
- Staff told us easy to read leaflets and large print or braille patient information was available and could be provided upon request.
- Following their examination, patients were given an explanation on aftercare. For example, cannulation sites and hydration. Patients were also provided with a copy of their scan results on compact disc (CD).

Access and flow

People could access the service when they needed it.

- The minimum patient appointment slot was one hour and two hours for spinal scans. The company's business plan dated August 2018 stated that the company aimed to accommodate one body part scanning appointments within 48 hours and two or more body part scan appointments within 72 hours.
- MRI images were available immediately upon completion of the scan, with the findings report delivered to the referring clinician and/or the patient within a 48 hour timeframe.
- Patients were referred to the service by health care professionals or could use a self-referral form on the company's website. NHS patient referrals were only accepted if the patient had a referral from a GP or healthcare professional and approved funding for their scan.
- Administrators contacted patients by telephone or email to arrange a convenient time and date for their appointment. Patients were emailed an appointment letter with details of their appointment and were encouraged to contact the centre if they had any concerns or questions about their examination. Staff told us appointments were usually within seven days.
- The radiography staff reviewed all referrals and confirmed the suitability of patients for scans. For complex cases the radiography staff could seek assistance from the clinical lead. Staff told us the centre was able to conduct an urgent scan if there was a request by a referring clinician or a patient.
- Staff told us there were very few delays and appointment times were closely adhered to. Referrals were prioritised by clinical urgency by radiography staff. Patients were often given an appointment within 48 hours. One patient we spoke with told us they had been offered an appointment within 48 hours of their initial visit to view facilities at the centre.
- Although the centre ensured imaging reports were shared in a timely fashion. The centre did not have key performance indicators that collated information on whether imaging reports were produced and shared in a timely fashion. The centre did not collate performance data such as: referral to appointment times, reporting turnaround times, the percentage of patients that had been contacted within five days of referral, the percentage and time it took on average for urgent referrals having an investigation report completed and the percentage of patients having a repeat activity due to incorrect or inadequate investigations. This meant the centre could not provide evidence of the responsiveness of the services it provided to patients.

- The centre did not have systems to collate information on whether patients that did not attend an appointment were subsequently scanned. Staff told us there had been no patients that had not attended a scan in the previous 12 months. Patients were informed in their appointment confirmation letter that there was a cancellation charge for appointments cancelled within 24 hours of the scheduled appointment time. Staff told us patients not attending appointments would be contacted to ascertain the reasons for their non-attendance and an appointment would be re-booked if requested. Staff told us referrers would be informed if patients did not attend appointments.

Learning from complaints and concerns

The service treated concerns and complaints seriously.

- Staff were encouraged to resolve complaints and concerns locally. The company had a complaints handling policy. However, this was not publicised either in the centre or on the company's website. Although, the website did have a 'drop down' menu on the company's 'get in touch' enquiries where patients could make an enquiry about complaints.
- Staff told us the centre had not had any complaints in the previous 12 months. Staff told us this was because patients were asked to provide feedback immediately following their scan and any concerns or issues raised by patients could be dealt with immediately. For example, staff told us the centre had purchased a stock of kosher biscuits following feedback from a patient. However, informal complaints and issues were not logged or recorded. Staff told us the administration manager reviewed patient feedback and could identify if there was a risk of recurring themes from informal patient feedback.

Are outpatients and diagnostic imaging services well-led?

Requires improvement

This was the first inspection for this service. We rated it as **requires improvement.**

Leadership

Managers had the right skills and abilities to run a service providing high-quality sustainable care.

- The centre was managed by a general manager, who was the registered manager and chairman of the board. They were supported by an operations manager, finance director, and administration manager. The management team also managed another of the provider's services in Manchester.
- The operations manager was recently new to the role. They were an experienced radiographer and had recently received an internal promotion to the operational manager's role in October 2018. The operations manager was enthusiastic and keen to improve the quality of services provided.
- We saw that managers had completed 'fit and proper' persons checks to ensure that managers were of good character, had the right competencies, skills and were physically and mentally fit for their role.
- Staff had specialist lead roles within the centre. For example, the operations manager was the lead for safeguarding and infection prevention and control (IPC), the general manager was the lead for health and safety and the administration manager was the lead for fire procedures. The operations manager was the allocated MRI responsible person.
- The operations manager and the clinical lead were responsible for the clinical functions of the unit. The operations manager was supported in their role by an experienced radiographer that supervised clinical work.
- The general manager was also the registered manager for the provider's centre in Manchester. This meant they divided their time between sites. However, staff we spoke with told us the manager was visible and approachable and they could contact them at any time by phone or email when they were not on-site. Staff said both the operations manager and the radiographer were approachable and supportive. All the staff we spoke with were positive about the management of the service.
- Medserena AG had a head office based in Cologne in Germany. Staff told us the head office had oversight of

the company's finances, but, were not involved in the governance of Medserena Upright MRI Centre in London. We saw finance managers from Germany on a visit to the service during our inspection.

- The medical physics expert was employed by Medserena AG and based in Cologne, Germany. The provider informed us that the medical physics expert visited the centre twice a year to review the scanning equipment in-situ, but these visits were not scheduled.

Vision and strategy

The vision and strategy was not based around the quality and safety of the service.

- Staff told us the company did not have any values which staff behaviours should be aligned to. Although, staff were aware of and told us about the company's mission statement. Staff told us the mission statement reflected the company's values. The mission statement was: "To enhance and improve the quality of life of people suffering pain, by delivering compassionate, competent and accessible high quality diagnostic services utilising innovative MRI technology, and to create a supportive team environment for patients, employees and clinical staff to foster learning and growth." Staff in the service understood the part they played in achieving the business aims of the service and demonstrated how their actions reflected the organisations mission statement.
- The company had a business plan dated August 2018. The next date for the business plan to be reviewed was recorded on the business plan as August 2019. The business plan contained the company's vision, which was, "We strive to be known as the "Provider of Choice" for Upright open MRI services in the UK." The business plan had a strategy. However, the strategy was based on a financial business model and did not address how clinical outcomes would be measured or monitored.
- Team meeting minutes dated 31 January 2018 reviewed strategies to support business growth and sales. However, the team meeting minutes did not demonstrate how the company's business growth and sales strategy was aligned to the company's mission statement. There was no record in the team meeting minutes that the clinical strategy had been reviewed at team meetings.

Culture

Managers promoted a positive culture that supported and valued staff. However, the provider could not be assured that there was an embedded culture of communicating in regards to incidents and complaints,

- Most of the staff we spoke with were very positive and happy in their role and stated the service was a nice place to work. Most staff we spoke with told us they felt supported, respected and valued on a local level. Staff said they were actively encouraged to make suggestions about changes and improvements to the services provided.
- Staff demonstrated pride in their work and the service they delivered to patients and their service partners. Staff told us they had sufficient time to support patients.
- Staff told us there was effective communication in the service from local managers. Staff said there was a small established staff group that had worked for the provider for a number of years and who knew each other well. Staff said they discussed issues in the centre on a daily basis. Staff told us there was a 'no blame' culture in regards to reporting incidents. However, the provider could not be assured that there was an embedded culture of staff identifying and communicating incidents, as staff told us about an incident that managers were unaware of.
- Managers told us informal site meetings were held weekly to discuss day to day working plans and schedules. These meetings were not minuted.
- Formal minuted team meetings were held regularly. However, there was no set schedule or terms of reference for the meetings. We were provided with minutes from the most recent three meetings. Staff told us team meeting minutes were emailed to staff following meetings. However, we found incident and complaints were not agenda items on the team meeting minutes. Managers confirmed that incidents and complaints were not on the agenda at team

meetings. Managers said this was because the service had not had any incidents or complaints. However, staff told us there had been an incident and this had not been reported. This meant the provider was missing an opportunity to put incidents and complaints on the agenda at team meetings, and embed a culture of reporting and sharing learning from incidents and complaints.

- Staff told us there were opportunities for continuing professional development (CPD) and personal development in the company. They also stated they were supported to pursue development opportunities which were relevant to the service. For example, managers were being encouraged to completed qualifications in leadership and management. Staff also told us teamwork was effective within the centre.
- Equality and diversity were promoted within the service and were part of mandatory training. There was a diverse staff team that promoted inclusive and non-discriminatory practices.
- The provider had a whistle blowing policy and duty of candour policy. This supported staff in raising concerns within the company. The policies also carried contact information for staff on external organisations they could contact in the event that they wished to escalate their concerns, including the CQC, information commissioner, and the charity Public Concern at Work.
- The centre told us 1% of their business was commissioned by the NHS. The centre also had two service level agreements (SLA) to provide services for NHS patients, although the centre told us they had not seen any NHS patients as a result of these agreements. The centre informed us that they used the Advisory, Conciliation and Arbitration Service (ACAS) document, 'Race discrimination: Key points for the workplace' for guidance on issues of workforce race equality as they did not think they were eligible for inclusion in the Workforce Race Equality Standard (WRES). Although not a requirement currently, the expectation moving forward will be that all providers will be expected to implement the WRES and submit data at a provider level to NHS England's WRES team on an annual basis.

Governance

The service did not use a systematic approach to continually improving the quality of its services.

- Managers told us there was a corporate and local governance framework. This included a framework of governance meetings; however, the provider could not be assured that governance processes provided oversight of service delivery and quality of care.
- Progress in the quality and safety of services was not monitored through key performance indicators (KPI), performance dashboards or reports that enabled comparisons and benchmarking of patient outcomes and risks with other services. Although, some data was collated this included the patient satisfaction survey and a finance spreadsheet. This gave the provider information on the centre's financial performance and patients satisfaction with services received.
- Quality monitoring was the responsibility of the general manager and operations manager. Staff told us clinical governance was not supported by Medserena AG as they were based in Cologne in Germany. Staff told us Medserena AG maintained financial oversight of the company.
- We reviewed team meeting minutes dated 31 January 2018, 22 June 2018, and 10 October 2018. We found the minutes recorded detail about the company's financial position, but, contained limited information in regards to clinical quality assurance and clinical risks. The team meeting minutes were generic to both the Manchester MRI centre and the London MRI centre.

Managing risks, issues and performance

The service did not have effective systems for identifying risks, or planning to eliminate or reduce them.

- Financial performance was monitored at a local and corporate level. This enabled financial benchmarking compared to other services in the provider's network. But, there was no formal system for monitoring clinical risks, issues and performance. The dashboard did not monitor incidents, complaints, or staff training.

- Managers told us risk, issues and performance were discussed on a regular, sometimes daily basis, at meetings or via email. Managers told us the business continuity plan acted as a risk register. This was reviewed annually.
- We viewed the centre's business continuity plan which could be used to detail mitigation plans in the event of the loss of access to the building, data and staffing. However, the business continuity plan was not specific in how the identified risks to business continuity would be mitigated.
- At the time of inspection we were told the centre did not have a risk register. Following our inspection the centre sent us a general risk assessment dated 14 March 2019. The risk assessment did not address clinical risks or some equipment risks, such as the wheelchair and toilet stand aid frame that did not have 'MRI unsafe' stickers, and the call alarm in the toilet on the scanning floor being inaccessible from the toilet. The risk assessment identified the operations manager as the owner of the risks on the risk assessment. The risk assessment did not detail the frequency of reviews of the general risk assessment. The provider could not be assured that actions were taken in a timely way to address or monitor all risks, issues and performance.
- We reviewed Medserena Upright MRI annual board meeting minutes dated 25 April 2017, 14 June 2018 and 2 July 2018. We found these were a review of the company's financial statements and 2 July 2018 minutes recorded the appointment of a new director. However, the minutes were not detailed and did not review clinical or other risks or clinical performance issues. The meetings recorded one attendee and this was the general manager, who was chairman of the board. The provider could not be assured all issues, risks or performance were actioned or monitored by the board.
- Staff told us the Medserena head office was based in Germany and was not subject to the same regulatory requirements in Germany as they were in the UK. Staff told us Medserena Upright MRI Centre had operated for five years without any significant adverse incidents to patients.

Managing information

The service used secure electronic systems with security safeguards.

- Patients' personal data and information was kept secure. Only authorised staff had access to patients' personal information. Patients' personal information was kept in locked cupboards. Administrators held the keys to the cupboards and these were only opened in response to a request from authorised staff and managers. Staff training on information governance was part of the provider's mandatory training programme.
- The service had access to the Medserena intranet where they could access policies and procedures.
- Staff told us there were sufficient numbers of computers in the centre. This enabled staff to access the computer system when they needed to.
- All staff we spoke with demonstrated they could locate and access relevant information and records easily, this enabled them to carry out their day to day roles. Patient records could be accessed easily but were kept secure to prevent unauthorised access to data.
- Information from scans could be reviewed remotely by referrers to give timely advice and interpretation of results to determine appropriate patient care.

Engagement

The service engaged well with patients and staff to plan and manage appropriate services.

- Staff satisfaction surveys were not undertaken. Managers told us due to the relatively small number of staff a staff survey would not be meaningful. Managers told us they engaged with staff on a daily basis.
- All patients were asked to provide feedback immediately following their scan. This involved the completion of a questionnaire. The administration manager monitored patient feedback. We viewed 10 patient feedback questionnaires and found all were positive about their experience of the service. We asked staff for examples of improvements to the service as a result of patient feedback. Staff gave us examples of the signage on the building at 114

Cromwell Road being enlarged to assist patients in identifying the centre's location and the centre's stocking kosher biscuits for patients with a kosher diet.

- The service had service level agreements (SLA) with two NHS trusts for the provision of upright MRI scans. However, managers told us they had not provided any care to patients as a result of these arrangements.

Learning, continuous improvement and innovation

The service was committed to promoting innovative approaches to patients care and treatment.

- The provider had a corporate strategy; this included an expansion programme whereby the provider would open upright MRI centres in London, Manchester and another location in the UK, yet to be identified.
- The provider specialised in the provision of MRI scanning for Ehlers-Danlos syndromes (EDS). The provider was the only provider of this type of specialist scanning in Europe.

Outstanding practice and areas for improvement

Areas for improvement

Action the provider MUST take to improve

- The provider must ensure staff follow the provider's incident reporting procedures.
- The provider must ensure all MRI unsafe equipment is labelled.
- The provider must ensure that patient call alarms are accessible to patients when using toilet facilities.
- The provider must ensure there are robust procedures for checks on equipment, including resuscitation equipment.
- The provider must ensure electrical safety testing is completed and a schedule of dates for equipment testing is in place.
- The provider must ensure appropriate processes are in place for the safe administration of contrast agents within the relevant legislation.
- The provider must ensure there are effective governance processes to assess, monitor and review risks and regulatory requirements.

Action the provider SHOULD take to improve

- The provider should ensure cleaning records are recorded daily, up to date, and copies kept.
- The provider should ensure hand hygiene audits are undertaken, recorded and copies kept.
- The provider should ensure all equipment including weighing scales are serviced and have a date when the next service is due.
- The provider should ensure there is a service level agreement for the external provision of level four children's safeguarding support and the procedure for accessing level four support are clearly documented in the provider's safeguarding policy.
- The provider should ensure there is a clearly documented incident reporting policy and procedure which is implemented and regularly monitored by the provider.
- The provider should have a process for sharing learning from incidents and complaints with all staff.
- The provider should ensure all staff have up to date training and knowledge of the Mental Capacity Act 2005 and associated guidance.
- The provider should ensure that the health and safety committee meets regularly and reviews regulations and guidance.

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 **Regulation 12 (2)(g) of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014: Safe Care and Treatment.** **(2) Without limiting paragraph (1), the things which a registered person must do to comply with that paragraph include;** 12 (2) (b) • Staff did not follow incident reporting procedures. Staff told us there had been an incident which staff had responded to, but, managers were unaware of the incident. Staff involved were aware of incident reporting procedures, but, did not report or document the incident. 12 (2) (e) • A toilet stand aid frame in a toilet on the scanning floor did not have a label to indicate to staff if the toilet stand aid frame was MRI safe. • A patient call alarm in the patient toilet could not be reached by patients using the facilities. • A first aid box in the kitchen contained a number of out of date dressings. There was no documented review schedule for the first aid box. Resus trolley items were stored randomly and there were items out of date in the resus trolley. There was a risk of staff inadvertently using the incorrect needle in a procedure as needle colours were stored in the same compartment in the resus trolley. Two sharps bins in the MRI observation area were open and had no information recorded, such as date.

This section is primarily information for the provider

Requirement notices

- Electrical safety testing had not been completed to ensure non-clinical electrical equipment was safe to use.

12 (2) (g)

- Contrast was administered but there were no records of prescriptions or PGD for the administration of contrast.

Regulated activity	Regulation
Diagnostic and screening procedures	Regulation 17 HSCA (RA) Regulations 2014 Good governance **Regulation 17 (1). Good governance** **Health and Social Care Act 2008 (Regulated Activities) Regulations 2014:** **17.—(1) Systems or processes must be established and operated effectively to ensure compliance with the requirements in this Part.** **(2) Without limiting paragraph (1), such systems or processes must enable the registered person, in particular, to—** 17 (2) (a) • There was a lack of effective governance processes to assess, monitor and review risks. 17 (2) (b) • There were no meetings or formal measures of performance, with the exception of financial performance. • Managers did not demonstrate a thorough awareness of their regulatory responsibilities.