Core Medical Solutions Ltd

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Inspection report

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

Ratings

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

Summary of findings

Overall summary

We have not rated this location previously. We rated it as inadequate because:

- Staff did not have training in key skills to understand how to keep patients safe and protect them from abuse. Staff did not assess risks to patients or act upon them. The service did not manage safety incidents well.
- The provider did not have effective systems to monitor the effectiveness of the service or make sure staff were competent.
- The provider did not maintain secure records in relation to persons employed in the carrying on of the regulated activities.
- The provider did not plan care to meet the needs of local people.
- Leaders did not run services using reliable information systems or support staff to develop their skills. The provider did not have an effective strategy to carry out its vision. The provider did not engage with the health community to plan and manage services and they were not committed to improving services continually.

However:

- The provider had enough staff to care for patients and keep them safe, staff controlled infection risk and kept good care records.
- Staff monitored patients pain and took action to relieve this as much as possible. Staff worked well together for the benefit of patients. Key services were available to suit patients' needs.
- Staff treated patients with compassion and kindness, respected their privacy and dignity, took account of their individual needs, and helped them understand their conditions. They provided emotional support to patients.
- The service took account of patients' individual needs. The service did not have control of whether people could access the service when they needed it and did not have to wait too long for treatment.
- Staff felt respected, supported and valued. They were focused on the needs of patients receiving care.

We are placing the service into special measures.

Services placed in special measures will be inspected again within six months. If insufficient improvements have been made such that there remains a rating of inadequate overall or for any key question or core service, we will take action in line with our enforcement procedures to begin the process of preventing the provider from operating the service. This will lead to cancelling their registration or to varying the terms of their registration within six months if they do not improve. The service will be kept under review and, if needed, could be escalated to urgent enforcement action. Where necessary another inspection will be conducted within a further six months, and if there is not enough improvement we will move to close the service by adopting our proposal to vary the provider's registration to remove this location or cancel the provider's registration.

Summary of findings

Our judgements about each of the main services

Service	Rating	Summary of each main service
Diagnostic and screening services	Inadequate 	We have not rated this service previously. We rated it as inadequate. See the summary above for details.

Summary of findings

Contents

Summary of this inspection

Background to Core Medical Solutions Ltd

Core Medical Solutions is a service which provides shockwave therapy to NHS patients across the United Kingdom. Extracorporeal shockwave lithotripsy (ESWL) is a treatment which uses shockwaves to break down stones in the kidney and urinary tract or to smooth joint surfaces. The shockwaves are produced by a machine and are focused onto the stone or joint surface using X-ray or ultrasound guidance. The waves pass through the skin and break up the stones into tiny fragments which come out when the urine is passed.

The service offers the treatment to adults.

The service operates from a base site in Norwich, East of England. Two mobile equipment units were based at this site, which comprised of a treatment table, lithotripter machine, X-ray and ultrasound machines that are transported to satellite sites based within host organisations. The service also provides one clinic, which is fixed. This means the equipment is permanently based at the host organisation.

This location has not previously been inspected. Findings from this inspection identified that the service was failing to comply with requirements of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014 Specifically Regulation 17, (1)(2)(a)(b)(d), Good governance. A warning notice has been served to the provider requiring that they make immediate improvements and comply by 10 October 2022. Please see areas for improvement section for further details.

How we carried out this inspection

Our inspection was announced (staff knew we were coming) to enable us to observe routine activity. We inspected this service using our comprehensive inspection methodology. One inspector and a specialist advisor, with support from an offsite inspection manager, carried out the inspection on 14 and 27 June 2022.

During the inspection we reviewed a range of documents related to running the service including, policies and procedures, the staff trainig matrix, patient feedback information and servicing records of equipment. We received completed questionnaires from six members of staff. We also reviewed three sets of patient records.

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

Areas for improvement

Action the service MUST take to improve:

- The provider must ensure all staff are provided with, have access to and undertake statutory mandatory and safeguarding training in relation to adults. Health and Social Care Act 2008 (Regulated Activities) Regulations 2014: Regulation 17(1)(2)(a)
- The provider must ensure a robust system of monitoring is in place including infection prevention and control, suitability and capability of staff to practice including data barring checks, professional registration checks and meaningful appraisals. Health and Social Care Act 2008 (Regulated Activities) Regulations 2014: Regulation 17(1)(2)(a)

Summary of this inspection

- The provider must ensure there are appropriate processes in place to support safe care and treatment including the recognition and management of deteriorating adults and children and incident reporting. Health and Social Care Act 2008 (Regulated Activities) Regulations 2014: Regulation 17(1)(2)(b)
- The provider must ensure there is a mechanism for monitoring the compliance and safety, quality and effectiveness of services provided in the carrying on of regulated activity. Health and Social Care Act 2008 (Regulated Activities) Regulations 2014: Regulation 17(1)(2)(a)
- The provider must ensure that consent is obtained and recorded in line with the relevant consent and decision-making requirements of legislation and guidance, including the Mental Health Act, Mental Capacity Act 2005. Health and Social Care Act 2008 (Regulated Activities) Regulations 2014: Regulation 11(1)
- The provider must ensure contracts and agreements, including service level agreements, are in place, current and contain in detail safety arrangements in line with statutory legislation. Health and Social Care Act 2008 (Regulated Activities) Regulations 2014: Regulation 17(1)(2)(d)
- The provider must ensure a robust process is in place to identify, monitor and act upon risk. Health and Social Care Act 2008 (Regulated Activities) Regulations 2014: Regulation 17(1)(2)(b)
- The provider must ensure there are appropriate governance processes in place, including audits, to monitor and assess the risks to people who use the service. Health and Social Care Act 2008 (Regulated Activities) Regulations 2014: Regulation 17(1)(2)(b)
- The provider must maintain securely such records as are necessary to be kept in relation to persons employed in the carrying on of the regulated activity Health and Social Care Act 2008 (Regulated Activities) Regulations 2014: Regulation 17(1)(2)(d)
- The provider must ensure patients are involved in serious incident investigations and provided with information about the incident and any actions the provider has taken. Health and Social Care Act 2008 (Regulated Activities) Regulations 2014: Regulation 20(1)(4)

Action the service SHOULD take to improve:

- The provider should consider the monitoring of access and flow data throughout the service to support delivery to meet individual needs.
- The provider should consult national guidance on implementing safety checklists for radiological procedures to ensure appropriate checks and records are completed.
- The provider should act on information provided in National Patient Safety Alerts (NPSA) and implement required actions by the required date.

Our findings

Overview of ratings

Our ratings for this location are:

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

Inadequate

Diagnostic and screening services

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

Are Diagnostic and screening services safe?

Inadequate

This service has not been inspected previously. We rated it as inadequate.

Mandatory training

The service did not provide all the necessary mandatory training in key skills to all staff and however, they made sure everyone completed it.

Staff received some mandatory training, although not all appropriate training, such as fire safety, was included. The Operations Manager and the registered manager were responsible for delivering training to staff. The Skills for Health core skills training framework, which ensures that staff have the basic knowledge required in key areas including health, safety and welfare, fire safety, infection prevention and control was not implemented within the service .

The provider did not have a specific mandatory training policy in place at the time of our inspection. This information formed part of another document that contained details of a range of other areas about the organisation. The information was not detailed enough to indicate specific training, training frequency or the training provider.

Staff told us they received and kept up-to-date with their mandatory training. They said training would be rebooked if it was not completed and they would not be able to work in their role until the training was completed.

Safeguarding

Staff did not receive adequate training on how to recognise and report abuse.

Staff had not received appropriate training, specific for their role, on how to recognise and report abuse in vulnerable adults. Staff had been given in-house training and following our inspection further safeguarding e-learning, although the Operations Manager was not able to tell us what level this was. This was not in line with the August 2018 Royal College of Nursing intercollegiate document Adult Safeguarding: Roles and competencies for health care staff. The document sets out the minimum requirements for all healthcare staff regardless of place of work. This is important because everyone has a responsibility to recognise and report abuse including "interactions causing concern" which could occur on the hospital corridor or in a waiting room.

The service had guidance for staff in their 'Safeguarding Adults Policy and Procedure' document. However, the provider had not updated all of their practice to follow the guidance.

The service did not meet Schedule 3 requirements of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014 in place to support safety in recruitment. For example, the provider was unable to show us pre-employment checks for members of staff, including reference checks. We saw that six staff members had a DBS check requested by the the provider, although the provider was not able to assure us these were obtained prior to these staff working with patients. The provider failed to provide any other information about pre-employment checks for their staff.

The provider had a recruitment policy in place. However, this did not contain any reference to the requirements of Schedule 3. The provider's recruitment checklist did refer to pre-employment checks and referred to another document, which we were not provided with.

At the time of our inspection there had been no safeguarding concerns raised by the service and the Operations Manager told us the hospital sites would deal with any concerns. Managers did not know about their reporting responsibilities.

Cleanliness, infection control and hygiene

The service generally controlled infection risk. Staff used equipment to protect patients, themselves and others from infection, although control measures were not all completed. They kept equipment and most of the premises visibly clean.

Cleaning records were up-to-date and demonstrated that all areas were cleaned. We observed appropriate cleaning being undertaken at one site during the inspection. Staff ticked and signed that they had completed cleaning of the machine prior to use. However, we observed the floor underneath moveable parts of the machine were dirty, and staff did not complete any forms to confirm that patient contact areas had been disinfected between cases.

The provider had not undertaken cleaning or hand hygiene audits. The National Institute for Health and Care Excellence (NICE) quality statement 61 on infection prevention and control highlights states, "Hand decontamination is considered to have a high impact on outcomes that are important to patients," and that, "Good practice is not universal." Without any local audit the service is not able to confirm whether required cleaning and hand hygiene standards were undertaken.

During our inspection visit we saw that staff undertook appropriate hand hygiene procedures.

Environment and equipment

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

The provider kept servicing and maintenance records for all equipment and sent us these records following the inspection. The records showed an electrical safety test, routine maintenance such as cleaning filters and injection nozzles as well as functionality tests of all equipment including the X-ray machine were undertaken annually in line with the Medicines and Healthcare Products Regulatory Agency managing medical device guidance.

Staff wore personal monitoring devices which were monitored by each trust, the service worked with. This was in line with The Royal College of Radiologists Implications for clinical practice in diagnostic imaging, interventional radiology and diagnostic nuclear medicine (IR(ME)R).

Staff carried out daily safety checks of specialist equipment. Staff ticked a box to show they had checked equipment before each session, however this did not show the different checks that were required. We were not assured that all the areas were checked, as specific check boxes serve as a reminder to staff of all the areas they need to review daily to ensure the correct working of each piece of equipment.

The service had enough suitable equipment to help them to safely care for patients. The provider had arrangements for portable lithotripsy machines to be available for all sessions scheduled at the different hospitals they visited. This was backed up with a spare machine in case of problems and meant staff were able to reschedule appointments, if needed, without waiting for repairs to be carried out.

Assessing and responding to patient risk

Staff did not complete or update risk assessments for each patient to remove or minimise risks. Staff did not have clear guidance to identify and act quickly towards patients at risk of deterioration.

The provider did not have adequate policies to support safe care and treatment, especially with regards to the care of the deteriorating patient. The provider did not have a deteriorating patient policy and relied on one paragraph within a document, titled 'Method Statement'. The registered manager told us staff relied on the referring hospital staff if they identified any deteriorating health in a patient. This limited information did not familiarise staff with the process at each individual site where services were provided. It meant that if a patient experienced a sudden deterioration in health, the provider could not be assured staff would respond appropriately if hospital staff were not immediately available.

There was guidance in place for staff in the management of patients using the service who were clinically unwell and required medical treatment. Staff told us they would refer the patient back to the hospital team within the department or use the emergency alarm. The registered manager told us the consultant urologist would be contacted. However, a clear procedure was needed to ensure staff were able to appropriately care for the patient while removing the machine if the patient was not able to help.

Staff did not form part of a safety huddle with the host organisations before the start of each clinic session. However, staff did review each patient's case notes before any treatment was started. The registered manager said they would raise any concerns with staff at the referring hospital. Staff had access to the picture archiving communications system (PACS), and the hospital's urologist would review any anomalies in images.

Staff undertook a verbal risk assessment of each patient before carrying out any treatment. This included the patient's name, date of birth, site of stone, whether the patient may be pregnant. Other checks, such as allergies, whether the patient had a pacemaker, comorbidities and contraindications, such as aspirin or other drugs affecting blood clotting were recorded by hospital staff. We saw that Core Medical Solutions Ltd staff checked this written information but they did not check again with the patient. During the inspection we observed this assessment take place with three patients. This meant that the right patient got the right treatment but staff relied on other people's completion of records to assess any additional risks to patients. None of this information was recorded in the service's own records, which did not follow WHO (World Health Organisation) checklist for procedures or the Royal College of Radiologists guidance.

Inadequate

Diagnostic and screening services

During the inspection we saw that staff reviewed key information during the patient introduction to keep patients safe. This included any important information such urine infection screening outcomes, blood pressure and pregnancy status.

Staffing

The service had enough staff to keep patients safe from avoidable harm and to provide the right care and treatment.

All clinical staff were registered allied health care practitioners in line with Schedule 2 of the Health and Social Care Act and the Ionising Radiation (Medical Exposure) Regulations IR(ME)R 2017, which entitles the practitioner to take responsibility for an individual's exposure. We reviewed service checks upon the Health and Care Professions Council.

Due to the specialist nature of the service, managers did not use bank and agency staff. Staff responded flexibly to changes in the rota for example to cover sickness or absence.

Staff turnover was low within the service, most members of staff had been employed for a year or more.

The provider monitored staff working and travelling hours to ensure they were following the Working Time (Amendment) Regulations 2003.

Records

Staff kept detailed records of patients' prior care and treatment. Records were clear, up-to-date, stored securely and easily available to all staff providing care.

A treatment record for each patient was written by the radiographer. We reviewed three patient treatment records during the inspection and found them to detail the treatment the patient had received such as, positioning, exposure factors and type of treatment. This was in line with the record management code of practice for health and social care workers, and IR(ME)R (Ionising Radiation (Medical Exposure) Regulations) requirements.

The records were then shared with the host organisation whilst a copy was kept at the base of the service. Managers told us these records kept for data requirements only and so information relating to any audit of the documents could be reviewed.

Medicines

The service did not administer medicines.

Incidents

The service did not manage patient safety incidents well. Staff recognised incidents and near misses and reported them appropriately. Managers investigated incidents and shared some lessons learned but adequate actions were not taken. Managers did not ensure that actions from patient safety alerts were implemented and monitored.

Staff raised concerns and reported incidents and near misses. Managers told us there had been one major incident within the last 18 months, when a patient and treatment table top had fallen to the floor. The Operations Manager told us that staff had received feedback from the investigation of the incident and were all aware of what had occurred. However, although marking the table top/mattress with where patients should sit had been considered, no action had

Inadequate

Diagnostic and screening services

been taken to consider other options when this action was ruled out. The provider sent us a risk assessment with an interim review date of January 2022 that included the set up of mobile lithotripsy machines. The assessment had not been updated to include the risk of patients falling from the table, despite this having happened, or the risk of a change in structure associated with moving and transporting equipment.

They also kept a record of minor incidents that staff reported, such as running out of gel. The Operations Manager told us staff usually found their own solutions to these incidents and information was cascaded to other staff during bi-monthly meetings and in the staff social media group.

Managers investigated incidents and the Operations Manager told us how they had determined what had happened during their major incident. However, the patient was not involved in the investigation, which did not comply with NHS England's Serious Incident guidance key principle for services to be open and transparent.

Incident reporting at the service was unclear because of the lack of clarity of working practices with the various host organisations. Clear guidance to staff and arrangements with hospitals was not in place to ensure that staff understood when, who to and how to report incidents. Therefore, safety monitoring, duty of candour and learning from incidents could not be applied appropriately within the service.

The UK Health Security Agency issued a safety alert in November 2021 in regard to the storage of ultrasound gel and required that actions, including storing gel in large containers cease by 31 January 2022. We saw, and the registered manager confirmed, they were still carrying out the practice of storing ultrasound gel in a large container and decanting to smaller containers for use when treating patients.

Are Diagnostic and screening services effective?

Inspected but not rated

This service has not been inspected previously. We rated it as inspected but not rated.

Evidence-based care and treatment

The service could not show it provided care and treatment based on national guidance and evidence-based practice. Managers did not formally check to make sure staff followed guidance.

The provider did not have a clinical audit programme in place to support and monitor national best practice guidance such as the National Institute for Health and Care Excellence (NICE), infection control and record management. There was no formalised process in place to provide assurance to itself that best practice guidance was followed. Local audit programmes are important to identify learning outcomes, so that improvement to clinical practice can be monitored and reviewed. According to the Society of Radiographers guidelines for professional audit reviewing images is an essential first step in an ultrasound audit programme.

Managers told us that local audits were informal and held by spending a day with each radiographer however, the provider was not able to produce any information to demonstrate this had taken place.

Due to the specific nature of treatment undertaken by the service, there were no national audits that the service could participate in to benchmark itself against. The service did not review and contribute to the most up to date clinical information around Lithotripsy procedure.

Inadequate

Diagnostic and screening services

We saw that senior staff had difficulty finding electronic information, such as specific policies and guidance, during our inspection. We were therefore not assured that staff would be able to locate guidance in a timely way either.

Radiation used by the service was kept as low as reasonably practicable (ALARP). During the inspection we saw that doses of radiation and reference levels were recorded, screening factors were used and machines were adjusted individually to ensure a half dose and the size of the beam was as low as possible and staff wore radiation monitors which were analysed by a dedicated group adviser. This was in line with the Administration of Radioactive Substances Advisory Committee notes for guidance on the clinical administration of radiopharmaceuticals and use of sealed radioactive sources.

The provider did not have adequate processes in place to ensure there was no discrimination and the rights of people subject to the Mental Health Act 1983 (MHA) were protected. The provider's recruitment and safeguarding policies contained some guidance for staff to ensure there was no discrimination, including on the grounds of protected characteristics under the Equality Act. However, the information was specific to the policies they were about and did not provide any guidance in relation to care and treatment decisions. In fact, of all the data sent to us following this inspection, these were the only documents to refer to discrimination. The safeguarding policy was the only document to refer to the MHA, although these were references only. Staff did not receive specific training in these areas.

Nutrition and hydration

The service did not provide food or drink.

Pain relief

Staff assessed and monitored patients regularly to see if they were in pain. They supported those unable to communicate using suitable assessment tools.

Staff did not administer pain relief however monitored levels of pain throughout the treatment using the recognised Abbey pain scoring method. We observed staff undertaking this assessment on three occasions during inspection. There was a picture chart to indicate levels of pain for patients unable to verbally communicate level of pain. Pre-procedure analgesia was administered by hospital staff.

All but one staff member told us they asked patients about their pain score regularly throughout the procedure.

Patient outcomes

Staff did not monitor the effectiveness of care and treatment to ensure they were able to make improvements to achieve good outcomes for patients.

Managers advised that due the small window of contact with the patient, monitoring outcomes were difficult, this meant no annual audits of treatments were completed and that consistency of outcomes and whether they had met national expectation could not be measured.

No post treatment data or information had been requested from the host organisation, such as treatment complications including bleeding at 30+ days, mortality or re-admission to hospital. This is good practice to ensure complication rates can be measured and future treatments can be tailored to reduce the risk of reoccurrence.

Managers told us that local audits were informal and held by spending a day with each radiographer to make sure individual practice was of a suitable level. The provider sent us information following the inspection to demonstrate this had taken place.

Inadequate

Diagnostic and screening services

Competent staff

The service did not make sure staff were competent for their roles. Managers did not adequately appraise staff's work performance and hold supervision meetings with them to provide support and development.

Clinical staff were qualified to meet the needs of patients. All clinical staff were registered allied health care practitioners in line with Schedule 2 of the Health and Social Care Act and the Ionising Radiation (medical exposure) regulations IR(ME)R 2017 regulations, which entitles the practitioner to take responsibility for an individual exposure. The provider monitored the Health and Care Professionas Council (HCPC) register to ensure practitioners were still registered.

Arrangements for supporting and managing staff to deliver effective care and treatment were not always in place. Four of the six staff who responded to our questionnaire, told us they had received an annual appraisal, although two staff said they had not received this. The Operations Manager told us staff received annual appraisals every 12 months, however we were not able to view records of these. This meant the provider may have had oversight into the clinical practice and ability of its staff but could not support staff appropriately in retrospect as records were not available.

The registered manager said they provided clinical staff with training on the use of each lithotripsy machine. The provider sent us training records for two staff to show how this was done, including ongoing competence in areas such as, X-ray and ultrasound targeting proficiency.

Multidisciplinary working

Healthcare professionals did not formally work together as a team to benefit patients.

No formal multidisciplinary agreement was in place and staff did not hold regular meetings with leaders from the hospitals they provided services for.

Seven-day services

Key services were available to support timely patient care.

Staff could call for support from doctors and other disciplines during their hours of operation. All clinics were run with the support of hospital trust members of staff in the department. The service operated Monday to Friday between the hours of 9am and 5pm, although Core Medical Solutions staff took bookings seven days a week from 7.30am.

Health promotion

Staff did not give patients practical support and advice to lead healthier lives.

Staff did not offer post treatment advice or information to patients to support them in the days following their treatment. This was the responsibility of host organisation staff.

Consent, Mental Capacity Act and Deprivation of Liberty Safeguards

Staff did not support patients to make informed decisions about their care and treatment. They did not follow national guidance to gain patients' consent or know how to support patients who lacked capacity to make their own decisions or were experiencing mental ill health.

Staff did not receive training in the Mental Capacity Act and Deprivation of Liberty Safeguards. Which meant that information about proposed care and treatment may not be provided in a way that patients could understand, and staff would not know how to act in accordance with the requirements of the Mental Capacity Act 2005.

Inadequate

Diagnostic and screening services

All but one staff member told us they asked patients about their pain score regularly throughout the procedure as a response to our question about continued consent. Only one staff member told us they also asked if patients wanted to continue. Managers told us the responsibility to ensure patients were able to give an informed written consent would be made by the referring clinician or doctor.

We saw that although staff checked to ensure the consent form had been signed, no further checks were made with the patient to ensure they were still happy for the procedure to commence or continue. This directly contravenes Regulation 11 (Need for consent) Health and Social Care Act 2008 (Regulated Activities) Regulations 2014: which sets out that consent must be given before any care and treatment is provided and that consent must be treated as a process that continues throughout the duration of care and treatment, recognising that it may be withheld and/or withdrawn at any time.

Although consent may be implied, the service did not have any method of assessment, recording or monitoring of consent implied or otherwise and no policy or procedure in place to for obtaining consent to care and treatment.

Are Diagnostic and screening services caring?

Good

This service has not been inspected previously. We rated it as good.

Compassionate care

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

Staff were discreet and responsive when caring for patients; they took time to interact with patients in a respectful and considerate way. Staff followed their own policies to keep patient care and treatment confidential.

Staff helped maintain the privacy and dignity of patients making sure other people could not enter the room during treatment.

Patients gave overwhelmingly positive responses to the provider in returned questionnaires in regard to their interaction with staff. Some patients added comments, such as, “Lovely staff,” and “Friendly service.”

Emotional support

Staff provided emotional support to patients, families and carers to minimise their distress.

Staff gave patients emotional support and advice when they needed it. We saw this during the inspection, with staff taking the time to talk to patients about things which were important to them other than the treatment they were undergoing. This helped as the patient was distracted and felt comfortable during their procedure.

Staff understood the emotional and social impact that a person’s care, treatment or condition had on their wellbeing. One patient’s feedback to the service said, “Made me feel at ease,” when asked about staff.

Understanding and involvement of patients and those close to them

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

Inadequate

Diagnostic and screening services

Staff made sure patients understood their care and treatment. We saw the treatment was explained by the radiographer from Core Medical Solutions, who was good at communicating what was happening. The radiographer explained every time the shock rate was changed or a movement was needed.

Patients could give feedback on the service and their treatment and staff supported them to do this. Patients' responses in questionnaires from the service were positive and showed their questions were answered to their satisfaction. Comments included, "Thanks for talking me through it all," and "Thank you for distracting me."

Are Diagnostic and screening services responsive?

Good

This service has not been inspected previously. We rated it as good.

Service delivery to meet the needs of local people

The service planned and provided care in a way that met the needs of local people and the communities served. It also worked with others in the wider system and local organisations to plan care.

Hospital staff scheduled clinics in advance to support the demand of patient care. The service worked flexibly to accommodate, where possible, additional requests for urgent cases from hospitals and scheduled clinics based on the availability of both equipment and staff. This supported the hospital trusts' COVID-19 recovery plans to help reduce any backlog of patients waiting for this treatment.

The service minimised the number of times patients needed to attend the hospital, by ensuring patients had access to the required tests on each occasion. Small dose radiation X-rays were taken to check the position of stones before treatment began. If staff were unable to locate a stone that had previously been treated, future sessions were cancelled as it was deemed the treatment had worked.

Meeting people's individual needs

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

Hospital staff provided patients with information explaining what to do if they experienced any complications or needed any post treatment support. The service did not provide written guidance to patients.

Translation services were available by a telephone-based service, however these would be arranged and provided by hospital staff before patients arrived for their treatment.

Patient positioning was an important feature of the shockwave therapy and staff took time to discuss and support patients into the most appropriate position.

Access and flow

People could access the service when they needed it and received the right care promptly.

Inadequate

Diagnostic and screening services

Host hospital staff the managed the booking of patients due to undergo lithotripsy treatment with the service. The service staff did not know until they were provided with a patient list on the day of treatment who was scheduled to attend. This meant that the service could not monitor national referral to treatment times.

The service did not monitor cancelled or missed appointments by patients.

Learning from complaints and concerns

People were able to give feedback and raise concerns about care received.

The provider had a process in place for managing complaints, although none had been received in the 12 months before this inspection. The Operations Manager told us complaints may be managed by each hospital's complaints department, depending on which organisation the complaint was made to. However, there were no formal agreements in place to provide guidance about this. They also told us there were no arrangements in place for the independent review of complaints, although they would put these arrangements in place if needed.

Patient feedback forms did not contain any questions about complaints, although all patients were happy with the care and treatment they received from Core Medical Solutions. However, this feedback was gained immediately following treatment, which did not then provide patients with the opportunity to raise concerns after the had reflected on their experience.

Are Diagnostic and screening services well-led?

Inadequate

This service has not been inspected previously. We rated it as inadequate.

Leadership

Leaders did not have the managerial skills or abilities to run the service. They failed to understand or manage the priorities and issues the service faced. They did not support staff to develop their skills and take on more senior roles.

The service had two leaders; the registered manager who was a radiographer with experience of lithotripsy, and the Operations Manager. The leaders were both based at the service headquarters but travelled to work clinically with patients.

Both leaders spoke weekly in person and by telephone to discuss staffing issues and travel plans. They carried out one to two monthly management review meetings to discuss actions identified in previous meetings, performance and conformity of products and services, resources and opportunities for improvement. Minutes were available for these meetings, which provided a record of discussions and decisions made by the leaders.

However, the registered manager was not clear about their role or accountability for the governance of the service. Risks were not identified and checks to ensure the safety of patients and staff were not well recorded. The registered manager could not articulate the risks, issues and challenges the service faced or locate records stored electronically. This meant that there could be unidentified risks within the service and missed opportunities for improvement.

Inadequate

Diagnostic and screening services

Leaders were not clear about their roles or their accountability for quality. We saw there was only one clinical audit in place. There was a limited approach to monitoring, reviewing or providing evidence against delivery of service plans or quality of care. Patient feedback was obtained and the provider showed us that they contacted one consultant about their working relationship. However, other outcomes were not monitored and wider engagement with key stakeholders was not formally undertaken. This meant that the service was not gathering assurance of quality care delivery across all services or showing how this would drive improvement.

On inspection we saw some succession planning, the need to develop leaders had been identified, and some action had been taken, although this had not been formally recorded.

The leadership team was stable and staff turnover was low. Leaders practiced clinically, making them both visible and accessible to staff members.

Vision and Strategy

The service had a vision for what it wanted to achieve, although their strategy was not focused on sustainability of services or aligned to local plans within the wider health economy.

The service had a strategy in place at the time of the inspection and there was a statement of guiding values. The Operations Manager told us they were not able to benchmark against other providers of similar services, yet the provider's strategy relied heavily on alleged poor performance by it's competitors. This meant there was a lack of meaningful or measurable plans for the delivery or improvement of the service.

Culture

Staff felt respected, supported and valued. They were focused on the needs of patients receiving care. The service had an open culture where patients and staff could raise concerns without fear.

Staff satisfaction was positive. They told us the culture of the service was, "Open, professional and friendly," "Inclusive, team centred, and friendly," and "Comfortable and welcoming." Staff said leaders were visible and were very communicative, with one staff member explaining they were able to speak in a number of different methods, such as, by phone or in an online chat.

Staff felt able to ask questions and speak with managers when they needed to. One staff member told us, "[The] Service is very important to us and I personally strive to give our patients the best we can." Patients also said questions they had during treatment were answered.

Governance

Leaders did not operate effective governance processes, throughout the service or with partner organisations. Staff had regular opportunities to meet, discuss and learn from the performance of the service.

Leaders were unable to produce employee records to meet the requirements of Schedule 3 of the Health and Social Care Act 2008 such as employment references or CV's. The data barring service (DBS) checks had not been appropriately completed for all employees. This was outside of Department of Health and Social Care sector specific guidance that healthcare workers should be checked every three years. Regular DBS checks are important. They are in place to safeguard vulnerable adults and children, to protect them and keep them free from harm.

Inadequate

Diagnostic and screening services

We found the provider did not have a process in place to identify effective patient outcomes to look at consistency of treatment or consider complications following treatment. We were not assured they were following national guidance and we were not assured they adequately monitored the safety of or risks to the service.

Service level agreements set out roles, responsibilities and accountabilities for patient care and safety whilst carrying out regulated activities within host organisations. The Operations Manager told us the hospitals they worked with had worked on purchasing orders as the NHS framework had only recently come into place, only one hospital had an agreement in place. However, since the inspection the provider has sent us information to show they had some of the relevant contracts or service level agreements with hospitals in place at the time of the inspection.

Contract meetings with host organisations did not take place in person due to the COVID-19 pandemic. The provider told us after the inspection that these meetings were held over Zoom and by telephone. However, they did not provide evidence to show the outcome of these discussions or whether any action was identified.

Staff all told us they attended bi-monthly meetings and these gave them the opportunity to share findings and knowledge. One staff member told us these were recorded electronically, which they could watch if they had missed a meeting.

Management of risk, issues and performance

Leaders did not use systems to manage performance effectively. They had not identified and escalated relevant risks and issues or identified actions to reduce their impact. They did not have plans to cope with unexpected events.

At the time of inspection, the service was only able to demonstrate limited processes or records of identified risks.

Following the inspection, the service provided a range of policies and guidance relating to assessing risk. The documents in place prior to our inspection did not contain clear enough guidance on the management of risk. Nor did the new documents recognise risks from previous incidents or how these should be mitigated in future.

The provider said they completed a risk assessment for treatment rooms that equipment was to be placed into every time a room changed or they started working in a new hospital. Following the inspection the provider sent us a risk assessment for moving a machine in and out of one hospital. While this assessment covered most aspects of this procedure, it did not include risks identified from previous incidents. This meant that risk assessments had not been adequately performed prior to the inspection so the opportunity to identify and act upon potential risks had been missed.

Lack of audit data and patient outcome monitoring also meant the provider had little oversight around the quality and effectiveness of the service.

The provider sent us their business continuity and contingency plan, which provided information about how the staff and the service would cope with unexpected events. They also sent other documents, such as their 'IR(ME)R 2017' document that contained contingency plans for overexposure of radiation.

Information Management

The service did not collect reliable data and analyse it. Staff could not find the data they needed, in easily accessible formats, to understand performance, make decisions and improvements. The information systems were not integrated.

Inadequate

Diagnostic and screening services

The service did not collect or analyse reliable data. For example, only one clinical audit and no operational audits were undertaken. Staff recorded copper plate test results, which made sure radiation exposure was at an acceptable level before patients received any X-rays. However, we saw this was a single exposure. It is good practice to take several exposures so that an average reading could be taken to ensure consistency with exposures. The Operations Manager said the registered manager oversaw these figures and staff would alert them to any adverse recordings. None of this analysis was recorded though.

We received three audits of outcome data following the inspection, which showed good outcomes for patients. However, these documents were created after the inspection, and therefore the provider had not used information for improvement or assurance.

Information and technology systems were not always used effectively. For example, leaders found it difficult to access information on their electronic system. The Operations Manager told us many files were still in paper format, such as recruitment checks, but they were unable to produce these either.

Engagement

Leaders and staff actively and openly engaged with patients and staff to plan and manage services. They collaborated with partner organisations to help improve services for patients.

The provider had set up a secure social media group for managers to communicate with staff members as well as telephone and byemail. Staff all said they were asked their views of the service and any comments were listened and acted upon. One staff member told us, “The company is always open to ideas and suggestions.”

Staff asked patients to complete a feedback questionnaire electronically. The collated information showed patients were very happy with the care and treatment staff provided.

Learning, continuous improvement and innovation

Leaders were not committed to continually learning and improving the service. There was poor understanding of quality improvement methods and the skills to use them. Leaders did not encourage innovation or participation in research.

The provider and registered manager did not display quality improvement, knowledge or associated use of its methodology to continuous learn and improve. The provider had developed an improvement tool in response to an ISO9001 audit earlier in 2022, however we continued to have concerns about the provider’s improvement methods at the time of our inspection.

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 17 HSCA (RA) Regulations 2014 Good governance • The provider must ensure all staff are provided with, have access to and undertake statutory mandatory and safeguarding training in relation to adults. Health and Social Care Act 2008 (Regulated Activities) Regulations 2014: Regulation 17(1)(2)(a) • The provider must ensure a robust system of monitoring is in place including infection prevention and control, suitability and capability of staff to practice including data barring checks, professional registration checks and meaningful appraisals. Health and Social Care Act 2008 (Regulated Activities) Regulations 2014: Regulation 17(1)(2)(a • The provider must ensure there are appropriate processes in place to support safe care and treatment including the recognition and management of deteriorating adults and children and incident reporting. Health and Social Care Act 2008 (Regulated Activities) Regulations 2014: Regulation 17(1)(2)(b) • The provider must ensure there is a mechanism for monitoring the compliance and safety, quality and effectiveness of services provided in the carrying on of regulated activity. Health and Social Care Act 2008 (Regulated Activities) Regulations 2014: Regulation 17(1)(2)(a) • The provider must ensure contracts and agreements, including service level agreements, are in place, current and contain in detail safety arrangements in line with statutory legislation. Health and Social Care Act 2008 (Regulated Activities) Regulations 2014: Regulation 17(1)(2)(d)

This section is primarily information for the provider

Requirement notices

- The provider must ensure a robust process is in place to identify, monitor and act upon risk. Health and Social Care Act 2008 (Regulated Activities) Regulations 2014: Regulation 17(1)(2)(b)
- The provider must ensure there are appropriate governance processes in place, including audits, to monitor and assess the risks to people who use the service. Health and Social Care Act 2008 (Regulated Activities) Regulations 2014: Regulation 17(1)(2)(b)
- The provider must maintain securely such records as are necessary to be kept in relation to persons employed in the carrying on of the regulated activity Health and Social Care Act 2008 (Regulated Activities) Regulations 2014: Regulation 17(1)(2)(d)

Regulated activity	Regulation
Diagnostic and screening procedures	Regulation 11 HSCA (RA) Regulations 2014 Need for consent • The provider must ensure that consent is obtained and recorded in line with the relevant consent and decision-making requirements of legislation and guidance, including the Mental Health Act, Mental Capacity Act 2005. Health and Social Care Act 2008 (Regulated Activities) Regulations 2014: Regulation 11(1)

Regulated activity	Regulation
Diagnostic and screening procedures	Regulation 20 HSCA (RA) Regulations 2014 Duty of candour • The provider must ensure patients are involved in serious incident investigations and provided with information about the incident and any actions the provider has taken. Health and Social Care Act 2008 (Regulated Activities) Regulations 2014: Regulation 20(1)(4)

This section is primarily information for the provider

Enforcement actions

Action we have told the provider to take

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

Regulated activity	Regulation
Diagnostic and screening procedures	S29 Warning Notice 1. We were not assured there were effective systems to assess, monitor and improve the quality and safety of the services provided in the carrying on of the regulated activity. 2. We were not assured there were effective systems to assess, monitor and mitigate risks relating to the health, safety and welfare of service users and others who may be at risk which arise from the carrying on of the regulated activity. 3. We were not assured that secure records were maintained in relation to persons employed in the carrying on of the regulated activities.