Impact Medical Limited

Impact Medical Limited

Inspection report

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

Ratings

Overall rating for this location	Inadequate
Are services safe?	Inadequate
Are services effective?	Inspected but not rated
Are services 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 and infection risk was not well controlled.
- The service did not have effective systems to monitor the effectiveness of the service or make sure staff were competent. Staff were not trained to support patients to make decisions about their care.
- The service did not maintain secure records in relation to persons employed in the carrying on of the regulated activities.
- Leaders did not run services using reliable information systems or support staff to develop their skills. Staff did not understand the service's vision and values, or how to apply them in their work. The service did not engage with patients and the community to plan and manage services and all staff were not committed to improving services continually.

However:

- The service had enough staff to care for patients and keep them safe and kept good care records.
- Staff monitored pain and patients were given pain relief when they needed it. Staff worked well together for the benefit of patients, advised them on how to lead healthier lives. 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, families and carers.
- The service took account of patients' individual needs. The service did not plan care to meet the needs of local people. 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

Summary of findings

Our judgements about each of the main services

Service	Rating	Summary of each main service
Diagnostic imaging	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 Impact Medical Limited

Impact Medical Limited is a service which provides shockwave therapy to both NHS and private sector 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. The shockwaves are produced by a machine and are focused onto the stone 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 both adults and children notably undertaking two child clinics per month at two dedicated children's hospitals.

The service operates from a base site in Merseyside, North West England. From here four sets of mobile equipment comprising of a treatment table, X-ray and ultrasound machines are transported to satellite sites based within host organisations. Two clinics are fixed meaning the equipment is permanently based within the host organisations.

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. Regulation 12 safe care and treatment, Regulation 11 need for consent and Regulation 17, Good governance.

A warning notice has been served to the provider requiring that they make immediate improvements and comply by 1st July 2022. In addition, requirement notices have also been issued to the provider requiring they take steps to improve standards. Please see areas for improvement section for further details.

How we carried out this inspection

Our inspection was unannounced (staff did not know we were coming) to enable us to observe routine activity. We inspected this service using our comprehensive inspection methodology. Two inspectors, with support from an offsite inspection manager, carried out the inspection on 23 May 2022.

During the inspection we reviewed a range of documents related to running the service including, a staff members recruitment pack, an independent website browser platform and servicing records of equipment. We spoke with five members of staff including the registered manager and five patients who had used the service. We also reviewed 15 sets of patient records and staff 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 is necessary to comply with its legal obligations. Action a service SHOULD take is because it was not doing something required by a regulation but it would be disproportionate to find a breach of the regulation overall, to prevent it failing to comply with legal requirements in future, or to improve services.

Action the service MUST take to improve:

Summary of this inspection

- The service must ensure all staff are provided with, have access to and undertake statutory mandatory and safeguarding training in relation to both adults and children. Health and Social Care Act 2008 (Regulated Activities) Regulations 2014: Regulation 12(1)(2)(b)
- The service 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 12(1)(2)(b)
- The service must assess the risk of, preventing, detecting and controlling the spread of, infections. Health and Social Care Act 2008 (Regulated Activities) Regulations 2014: Regulation 12(1)(2)(h)
- The service must assess the risks to the health and safety of service users of receiving the care or treatment including pre-employment and professional registration checks. Health and Social Care Act 2008 (Regulated Activities) Regulations 2014: Regulation 12(1)(2)(a)
- The service 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 and the Children Acts 1989 and 2004. Health and Social Care Act 2008 (Regulated Activities) Regulations 2014: Regulation 11 (1)
- The service 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 1717(1)(2)(a)
- The service must ensure contracts and agreements including service level agreements and practicing privilege arrangements 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 service 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 service must ensure there are appropriate governance processes in place including appropriate and in date policies and procedures, statement of purpose and human resource risk assessments. There must also be records of meetings undertaken Health and Social Care Act 2008 (Regulated Activities) Regulations 2014: Regulation 17 17(1)(2)(d)
- The service 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 17(1)(2)(d)

Action the service SHOULD take to improve:

The service should consider the monitoring of access and flow of data throughout the service to support delivery to meet individual needs such as cancelled or missed appointments.

Our findings

Overview of ratings

Our ratings for this location are:

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

Inadequate

Diagnostic imaging

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

Are Diagnostic imaging safe?

Inadequate

Mandatory training

The service did not provide mandatory training in key skills to any staff.

Staff within the service did not receive mandatory training. Managers at the service told us that mandatory training was not in place This was not in line with the Skills for Health core skills training framework which was designed to protect patients and the public by ensuring that staff have the basic knowledge required in key areas including health, safety and welfare, fire safety, infection prevention and control and resuscitation.

The service did not have a mandatory training policy in place at the time of our inspection.

Safeguarding

Staff did not understand how to protect patients from abuse. Staff did not receive training on how to recognise and report abuse.

No staff received training on how to recognise and report abuse in children. Out of the eight members of clinical staff only three had completed any training on children's safeguarding. This was not in line with the January 2019 Royal College of Paediatric and Child Health intercollegiate document Safeguarding children and young people: Roles and competencies for healthcare staff. The document sets out the minimum level one requirement 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 and may relate to a child accompanying an adult not specifically attending for treatment.

During the inspection we reviewed the staff rota's between March and May 2022 and saw that the three members of staff who had completed the children's safeguarding training undertook all the clinics carrying out treatment on children.

A manual kept with each machine contained information on how to report a safeguarding incident. The first point of contact was the registered manager for the service who was also the designated safeguarding lead for the service and had completed an adult and children's level three safeguarding training course.

The service had a guidance for staff safeguarding adult's policy and procedure document. However, this was the original document submitted to the Care Quality Commission prior to registration and had not been updated or amended, it did not contain a date for review, referenced outdated guidance from 2000 and terminology such as CRB checks and listed the emergency contact details of the deputy designated named person who no longer undertook this role.

There was no safeguarding children policy.

The service did not meet Schedule 3 requirements of the Health and Social Care Act 2008 in place to support safety in recruitment. For example, the service was unable to provide pre-employment checks for clinical members of staff including reference checks, and although a recruitment file was in place for a new non clinical member of staff no data barring check had been undertaken despite this member of staff being required to attend host organisations in the event of a failure in equipment. Managers told us the last member of clinical staff started working for the service six years ago.

At the time of our inspection there had been no safeguarding concerns raised by the service and staff told us the hospital sites would deal with any concerns.

Cleanliness, infection control and hygiene

The service did not control infection risk well. The service did not use control measures to protect the patients. However, staff kept equipment and the premises visibly clean.

Staff completed a cleaning and disinfectant log at each site. This was a paper form which included the type of disinfectant that was used, the name of the driver and radiographer and a tick box to confirm that patient contact areas had been disinfected between cases. We observed the appropriate cleaning being undertaken at one site during the inspection and reviewed four cleaning logs for May 2022 all were ticked and signed.

However, no local cleaning or hand hygiene audits were undertaken. The National Institute for Health and Care Excellence quality statement 61 on infection prevention and control highlights that "hand decontamination is considered to have a high impact on outcomes that are important to patient" and that "good practice is not universal". Without any local audit the service is not able to determine whether required cleaning and hygiene standards were undertaken.

Environment and equipment

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

The service kept installation and maintenance records for all equipment. During the inspection the provider was unable to provide the records however did produce them 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 devise guidance.

Engineering staff employed at the service had undertaken specialised training to support the maintenance and repair schedule. Following our inspection, we saw the training certificates of one manager of the service and they confirmed course dates of a new member of the engineering team and servicing documents and fault logs were kept for each piece of equipment.

Inadequate

Diagnostic imaging

Staff wore personal monitoring devices which were monitored by an external group advisor in line with The Royal College of Radiologists Implications for clinical practice in diagnostic imaging, interventional radiology and diagnostic nuclear medicine (IR(ME)R

Assessing and responding to patient risk

Staff did not identify and quickly act upon patients at risk of deterioration. However, Staff did complete and update risk assessments for each patient to remove or minimised risks.

There was a lack of policies to support safe care and treatment especially with regards to the care of the deteriorating patient.

The service did not have a deteriorating patient policy and did not familiarise staff with the process at each individual site it provided services for. This meant that if a patient experienced a sudden deterioration in health, the service could not be assured staff would recognise or respond promptly to protect the patient.

There was no specific pathway or process in place for staff in the management of patients using the service who were clinically unwell and required hospital admission. Staff told us they would refer the patient back to the host organisation team within the department and managers told us the urologist would be contacted via telephone although this was not written anywhere for staff to follow.

Staff did not form part of a safety huddle with the host organisations prior to the clinic. One manager told us that this did occur in the children's clinic however was not routine in the clinics treating adults. Staff did review the case notes of patients prior to the list commencing and raised any concerns with staff at the host organisation. Staff explained that safety netting was in place for image reviews as the majority had also been reported. Staff had access to the picture archiving communications system (PACS), and the urologist would review any anomalies in images.

However, staff undertook a risk assessment of each patient prior to carrying out treatment. This included name, date of birth, site of stone, whether the patient may be pregnant or have a pacemaker, comorbidities and contraindications such as aspirin or other drugs affecting blood clotting. During the inspection we observed this assessment take place in five patients and of review of a further 10 patient records. This meant that the right patient got the right treatment.

During the inspection we saw that staff from both the host organisation and from the service provider shared key information during the patient introduction to keep patients safe when handing over their care to each other. This included any important information such urine infection screening outcomes, pain levels and follow up information.

Staffing

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

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’s exposure. However, the service failed to monitor the register to ensure practitioners were still registered. We reviewed service checks upon the Health and Care Professions Council.

Inadequate

Diagnostic imaging

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 and managers had built into the rota a 'rest week' for all staff. This was every four weeks and designed to support the rest and retention of staff following an intense period of traveling throughout the other weeks.

Staff turnover was low within the service, all clinical members of staff had been employed for longer than five years.

The service did monitor staff working and travelling hours to ensure they were following the working time (amendment) regulations 2003.

Records

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

A treatment record for each patient was handwritten by the radiographer. We reviewed 15 patient treatment records during the inspection and found them to be clear, legible and comprehensive, detailing the care and treatment the service user 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.

The records were then shared with the host organisation whilst a carbon copy was kept at the base of the service. Managers told us an adhoc audit of records was undertaken but not documented and so information relating to this audit could not be reviewed.

Medicines

The service did not administer medicines

Incidents

The service did not manage patient safety incidents well. Staff did not recognise incidents and near misses or report them appropriately.

Incident reporting at the service was unclear because of the lack of clarity of working practices with the various host organisations. Managers told us there had been no incidents within the last 12 months however we heard an example of a patient whom had deteriorated whilst undergoing treatment within the last 12 months that had not been recorded as an incident. Clear guidance to staff and arrangements with host organisation was not in place to ensure that staff understood when, who to and how to report incidents. This meant safety monitoring, duty of candour and learning from incidents could not be applied appropriately within the service.

Are Diagnostic imaging effective?

Inspected but not rated

Evidence-based care and treatment

The service could not evidence that it provided care and treatment based on national guidance and evidence-based practice.

Inadequate

Diagnostic imaging

The service 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, 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 service 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 review and contribute to the most up to date clinical information around Lithotripsy procedure.

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.

Nutrition and hydration

Nutrition and hydration needs of service users were managed by the individual host organisations.

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 and gave additional pain relief to ease pain.

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 five 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 the host organisations staff.

Patient outcomes

Staff did not monitor the effectiveness of care and treatment or use the findings to make improvements and achieve good outcomes for patients.

Managers advised that due the small window of contact with the patient, monitoring outcomes was 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 and admittance to hospital.

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

Inadequate

Diagnostic imaging

Competent staff

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

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. However, the service failed to monitor the register to ensure practitioners were still registered. The last registration checks for all eight specialist radiographers had taken place on the 3rd February 2020. This meant the service could not be assured staff had continued registration with the relevant bodies.

In addition, systems within the service did not always protect people from abuse. For example, disclosure and barring service checks for four members of staff were last reviewed in 2018 whilst the other four were in 2016. This was outside of the Department of Health and Social Care expectation of checks every three years for healthcare staff and meant the service had no oversight of any convictions or listings on the enhanced barred list which was in place to protect vulnerable adults and children. At the time of the inspection, managers told us the service did not have a risk assessment or process in place to manage the return of such information however, the service demonstrated that one had been created shortly afterwards.

Arrangements for supporting and managing staff to deliver effective care and treatment were not in place. Both clinical supervision and annual appraisals had not been undertaken for any staff since 2019 which meant that the service had no oversight into the clinical practice and ability of its staff and could not support staff appropriately. An example of this was oversight of image interpretations, managers told us that this would be monitored at annual clinical supervision. No one to one meetings, coaching and mentoring took place.

Multidisciplinary working

Healthcare professionals did not formally work together as a team to benefit patients. They supported each other informally to provide good care.

The service held safety huddles at the beginning of each paediatric case. No formal multidisciplinary agreement was in place and the service did not hold regular meeting with leaders from the host organisations it provided services for. Managers told us they worked closely with consultant urologists when undertaking clinical work.

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 Saturday between the hours of 8am and 6pm.

Health promotion

Staff gave patients practical support and advice to lead healthier lives.

The service offered post treatment advice and signposting information to patients to support them in the days following their treatment. This was given to patients in the form of an information advice sheet following their treatment.

Inadequate

Diagnostic imaging

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 or were experiencing mental ill health to make their own decisions.

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.

Managers told us that "no impact medical radiographers would be involved or take part in the consent process for any patient. The responsibility for consenting and decision making would be made by the referring clinician or doctor". 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 imaging caring?

Good

Compassionate care

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

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

Staff helped maintain the privacy and dignity of all patients.

Patients said staff treated them well and were "brilliant". All five patients that we spoke to during the inspection were happy with the care they had received.

Emotional support

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

Staff gave patients 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 and on those close to them.

Inadequate

Diagnostic imaging

Understanding and involvement of patients and those close to them

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

Staff made sure patients understood their care and treatment. During the inspection, we observed five patients receiving their treatment. We saw that the treatment was explained in detail by both the senior sister from the host organisation and the radiographer from Impact Medical Limited

Staff talked with patients in a way they could understand, communication aids were available where necessary such as picture cards.

Staff supported patients to make informed decisions about their care. An example of this was when the treatment was not the most appropriate option for a patient. We saw that staff took time to explain and discuss this information and signpost the patient to ensure they got the most timely and relevant pathway of treatment instead. This was done in a caring and unhurried way.

Patients we spoke to during the inspection gave positive feedback about their experiences of the service. Of the five patients three had used the service before and all said they would recommend the service.

Are Diagnostic imaging responsive?

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.

Clinics were scheduled in advance to support the demand of patient care. The service worked flexibly to accommodate, where possible, additional requests for urgent cases from host organisations and scheduled clinics based on the availability of both equipment and staff. This supported the host organisations COVID-19 recovery plan to help reduce the backlog of patients waiting for this treatment.

Staff provided care in ways that met the needs of the patient. For example, we saw staff refer a patient, who did not meet the treatment criteria, onto another service to ensure a timely appointment and as fast a resolution as possible. The staff member worked hard to try and secure an appointment for that day to try and minimise the number of times the patient needed to attend the hospital.

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.

An information advice sheet was given to patients explaining what to do if they experienced any complications or needed any post treatment support.

Translation services were available via a telephone-based service.

Inadequate

Diagnostic imaging

No bariatric treatments were undertaken by the service due to specialised regional facilities managed by host organisations.

Double treatment sessions could be booked if required for patients with concerns, worries or anxieties and for patients with mobility issues requiring assistance accessing the treatment table. 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. Waiting times for treatment were monitored by the host organisation.

Host organisation managed the booking of patients due to undergo Lithotripsy treatment with the service. The service did not know until it was 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. Between May 2021 and May 2022, the service had not cancelled any appointments or clinics.

Learning from complaints and concerns

It was easy for people to give feedback and raise concerns about care received. The service treated concerns and complaints seriously, had processes to investigated them and share lessons learned with all staff. The service included patients in the investigation of their complaint.

The service had a process in place for managing complaints. It had not received any complaints between May 2021 and May 2022.

We spoke to five patients during the inspection and all knew how to raise concerns or give feedback and staff we spoke to, understood the process and explained how they would handle and escalate any concerns raised.

Are Diagnostic imaging well-led?

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 four leaders, all were radiographers with experience of Lithotripsy, and one was also an electrical engineer with experience of medical devices. The leaders were all based at the service headquarters but travelled often to work clinically.

There were no formal leadership meetings, leaders spoke weekly in person and by video conferencing mainly to discuss staffing issues and travel plans however, minutes or notes from these meetings were not made.

Inadequate

Diagnostic imaging

Leaders were not clear about their roles or accountability for the governance of the service. There were no formal reviews of the safety of the service by leaders. Leaders could not articulate the risks, issues and challenges the service faced. This meant that there could be unidentified risks within the service and missed opportunities for improvement.

Leaders were not clear about their roles or their accountability for quality. We saw there were no clinical audits in place, feedback from patients was not routinely gained and incident forms were not routinely completed. There was no approach to monitoring, reviewing or providing evidence against delivery of service plans or quality of care. Patient outcomes were not monitored and wider engagement with key stakeholders had not taken place. This meant that the service was neither gathering assurance of quality care delivery or how this would drive improvement.

On inspection we saw no succession planning, the need to develop leaders had not been identified nor acted on.

The leadership team was stable and staff turnover was low. Leaders practiced regularly on the front line and were both visible and accessible to staff members.

Vision and Strategy

The service did not have a vision for what it wanted to achieve, or a strategy developed with all relevant stakeholders to turn it into action. Therefore, the service was not assured it was aligned to local plans within the wider health economy.

The service did not have a strategy in place at the time of the inspection and there was no credible statement of vision or guiding values. This meant there was no meaningful or measurable plans for the delivery or improvement of the service.

Culture

The service had an open culture where patients, their families and staff could raise concerns without fear. Staff felt respected, supported and valued. They were focused on the needs of patients receiving care. The service did not actively promote equality and diversity in its daily work.

Staff satisfaction was positive, leaders were visible, and staff were proud to work for the organisation. We saw cooperation between leaders and staff particularly around the cover of absence.

Staff felt able to raise concerns without fear of retribution.

There was no evidence of active promotion of equality, diversity or inclusion within the service.

Governance

Leaders did not operate effective governance processes, throughout the service or with partner organisations. Staff at all levels were not clear about their roles and accountabilities or have regular opportunities to meet, discuss and learn from the performance of the service.

The service did not have the relevant contracts or service level agreements with the host organisations in place at the time of the inspection. Service level agreements set out roles, responsibilities and accountabilities for patient care and safety whilst carrying out regulated activities within host organisation. This information was requested for all host organisations where regulated activities were carried out however only one agreement was produced. This agreement had expired in May 2018 and was unsigned. This meant that there were no clear lines of accountability for the service provision.

Managers informed us that staff employed by the service worked under practicing privileges at one of the host organisations but were unable to produce copies of contracts regarding these arrangements or any checks undertaken by the service to maintain privileges. Practising privileges are well-established systems of checks and agreements to enable safe practice in host organisation such as hospitals without being directly employed by them.

Contract meetings with host organisations did not take place.

The service was unable to provide agendas or minutes of senior director or staff meetings and no additional policy or training had been put into place when the service commenced providing treatment for children after initial registration with the Care Quality Commission.

The data barring service (DBS) checks had not been completed since 2016 for employees and 2018 for leaders. This was outside of Department of Health and Social Care sector specific guidance that healthcare workers should be checked every three years and was also not in line with the services own management policy and procedure document which stated that DBS checks were recorded bi-annually. Regular DBS checks are important. They are in place to safeguard vulnerable adults and children, to protect them and keep them free from harm.

The service did have in place appropriate indemnity insurance.

Management of risk, issues and performance

Leaders and teams 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.

At the time of inspection, the service was unable to demonstrate any process or records of identified and acted upon risks.

Following the inspection, the service provided a general risk assessment relating to a host organisation. The document contained estimated risk of radiation including projected dose under normal working conditions, and accidental exposure. However, the service no longer offered services at this host organisation, the document had exceeded the review date of November 2021 and had listed actions with no evidence of completion. No further general risk assessments for other sites were provided.

Seven risk assessments were submitted following the inspection. These included infection, keyless X-ray units, manual handling and risk of radiation to potentially pregnant women. All had creation dates of the 24th May 2022 and did not demonstrate clear actions to reduce the level of risk. This meant that risk assessments had not been performed prior to the inspection so the opportunity to identify and act upon potential risks had been missed.

A further five risk assessments were provided by the service including working with children and radiographer lone working. These risk assessments had review dates due between March and August 2021. This meant the service could not be assured it had robust arrangements for identifying, recording and managing risks, issues and mitigating actions relating to health, safety and welfare.

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

Inadequate

Diagnostic imaging

Information Management

The service did not collect reliable data or 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 and secure.

The service did not collect or analyse reliable data. For example, clinical and operational audits were not undertaken, no outcome data or waiting time information was collected which meant that information was not used for improvement or assurance.

Information and technology systems were not always used effectively. For example, each leader could not access the entire system or local files such as recruitment packs, contracting information, servicing information and compliance data around data barring checks, appraisal and registration checks so if they were unavailable other leaders could not access the relevant information.

Engagement

Leaders and staff did not actively and openly engage with patients, staff, equality groups, the public and local organisations to plan and manage services. They did not collaborate with partner organisations to help improve services for patients.

A secure social media group was in place for managers to communicate with staff members as well as video conferencing and via email. The last team meeting had taken place prior the COVID-19 lockdown.

No evidence of formal engagement was undertaken with patients or the public at the time of our inspection.

Learning, continuous improvement and innovation

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

The service did not display quality improvement, knowledge or associated use of its methodology to continuous learn and improve. No improvement tools or methods were in place 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 12 HSCA (RA) Regulations 2014 Safe care and treatment 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 and infection risk was not well controlled.

Regulated activity	Regulation
Diagnostic and screening procedures	Regulation 11 HSCA (RA) Regulations 2014 Need for consent Consent was not obtained in line with Statuatory guidance and staff were not trained to support patients to make decisions about their care.

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	Regulation 17 HSCA (RA) Regulations 2014 Good governance Leaders did not run services using reliable information systems or support staff to develop their skills. Staff did not understand the service's vision and values, or how to apply them in their work. The service did not engage with patients and the community to plan and manage services and all staff were not committed to improving services continually.