

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

Good 

Are services safe?

Good 

Are services effective?

Inspected but not rated 

Are services caring?

Good 

Are services responsive to people's needs?

Good 

Are services well-led?

Good 

Summary of findings

Overall summary

Our rating of this location improved. We rated it as good because:

- Staff were competent and trained in key skills, safeguarding, assessing risks and reporting of incidents.
- Managers monitored the effectiveness of the service.
- Leaders had developed their leadership skills and were competent in how they ran the service using reliable systems and processes.
- Leaders had acted on feedback from the previous inspections and now met regulatory requirements.
- The service was engaged in research and innovation to improve outcomes for patients.

However:

- Safeguarding policies were not fully in line with up-to-date legislation.
- Although risks were recorded this was not in a consistent manner and did not enable tracking and monitoring.

Summary of findings

Our judgements about each of the main services

Service	Rating	Summary of each main service
Diagnostic imaging	Good 	Our rating of this service improved. We rated it as good. See the summary above for details.



Summary of findings

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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.

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. The service had treated a total of 2774 patients in the year prior to our inspection.

This service has previously undergone comprehensive and focussed inspections. A warning notice was served to the provider requiring that they make immediate improvements and comply by 1st July 2022 following the comprehensive inspection in May 2022. A focussed inspection took place in October 2022 to follow up on the required improvements from the warning notice.

This inspection in March 2023 showed that the service was now compliant with regulations and requirement notices had been met.

How we carried out this inspection

We inspected this service using our comprehensive inspection methodology. We carried out a short-announced inspection on 7 March 2023. The inspection included a visit to one of the service's locations in Merseyside.

The inspection team comprised of 2 CQC inspectors with the support of an inspection manager off-site.

During the inspection we reviewed a range of documents related to the running of the service. We spoke to staff of various roles and 3 patients about their experience. We reviewed policies relevant to the service, 10 patient records and 5 radiology reports.

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>.

Outstanding practice

We found the following outstanding practice:

- The service took part in external and independent research into the uses of shock wave therapy to improve patient outcomes for a wide range of health problems.

Summary of this 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 SHOULD take to improve:

- The service should ensure that safeguarding policies reference all current legislation and guidance.
- The service should ensure that leaders acting as the designated safeguarding lead for the service have the correct level of safeguarding training.
- The service should ensure that an appropriate method of recording risk is implemented.






Our findings

Overview of ratings

Our ratings for this location are:

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

Diagnostic imaging

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

Is the service safe?

Good 

Our rating of safe improved. We rated it as good.

Mandatory training

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

Staff received and kept up-to-date with their mandatory training, with all staff having completion rates of 100%.

The mandatory training was comprehensive and met the needs of patients and staff. The service had an electronic training system which all staff could access. Staff had been given time to undertake mandatory training modules which included key modules such as mental capacity awareness, dementia awareness, infection, prevention and control and health and safety awareness.

Clinical staff completed training on recognising and responding to patients with mental health needs, learning disabilities and autism.

Managers monitored mandatory training via the electronic system which alerted both the manager and staff when they needed to update their training. This meant that the service could ensure that training had been undertaken and staff had appropriate knowledge to meet the needs of patients in areas other than their specialist clinical field.

Safeguarding

Staff understood how to protect patients from abuse and the service worked well with other agencies to do so. Staff had training on how to recognise and report abuse and they knew how to apply it.

Staff received training specific for their role on how to recognise and report abuse. All staff had completed level 3 child and adult safeguarding training 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.

Staff knew how to identify adults and children at risk of, or suffering, significant harm and worked with other agencies to protect them.

Diagnostic imaging

The service had safeguarding children and adults' policies however these referenced outdated guidance from 2000.

Managers had enhanced disclosure and barring checks (DBS) for all staff and were signed up to the DBS automatic update service.

All staff both clinical and non-clinical were now subject to three yearly repeat DBS checks and two-yearly professional registration checks (where applicable) which were highlighted via the electronic training platform.

Staff knew how to make a safeguarding referral, who to inform if they had concerns and could give examples. Managers had created a 'director on call' structure so that there was always a point of contact to offer support and guidance to staff when required.

The registered manager for the service was the designated safeguarding lead but had not completed the correct level of training (level 3 instead of level 4) but this was in the process of being arranged.

We reviewed 3 staff recruitment files and found these did not always include all pre-employment checks including employment history, references and interview documentation as all staff had been employed at the organisation for 5 years or more. The service had introduced a policy following our first inspection that contained correct and appropriate recruitment processes and checks for future staff recruitment.

Cleanliness, infection control and hygiene

The service controlled infection risk well. Staff used equipment and control measures to protect patients, themselves and others from infection. They kept equipment and the premises visibly clean.

Clinical areas were clean and well-maintained. Staff completed a cleaning and disinfectant log at each site. This was a paper form which included the type of cleaning product that was used, the name of the driver and radiographer and a tick box to confirm that patient contact areas had been cleaned between cases.

The service generally performed well for cleanliness and cleaning records were up-to-date. Audits were undertaken of compliance with monthly deep cleaning of equipment so that the cleanliness of equipment could be monitored. The audit documentation we reviewed demonstrated that equipment was cleaned regularly.

The service had a comprehensive infection prevention and control policy that referred to up to date and relevant guidance.

Staff followed infection control principles including the use of personal protective equipment (PPE). All staff had completed training on hand hygiene in their infection prevention control mandatory training and a handwashing assessment was built into the annual clinical supervision. We observed staff decontaminating their hands in line with best in line with the National Institute Care Excellence (NICE) quality statement 61. Staff wore PPE appropriately and cleaned equipment and surfaces between patients.

Environment and equipment

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

Staff carried out daily safety checks of specialist equipment regularly and when installed at host organisations.

Diagnostic imaging

Engineering staff employed at the service had undertaken specialised training to support the maintenance and repair schedule of the specialised equipment.

The service maintained and serviced equipment appropriately. We reviewed installation and maintenance records for lithotripsy and X-ray equipment which included routine maintenance activities and functionality quality assurance testing of X-ray equipment in line with the Medicines and Healthcare Products Regulatory Agency managing medical device guidance.

Staff wore personal radiation monitoring devices which were monitored, and the service had appointed radiation protection supervisors and held a contract for radiation protection advisor and medical physics expert services in line with the Ionising Radiation Regulations 2017 (IRR17).

Staff disposed of clinical waste safely, we observed the correct use of appropriate waste bins.

Assessing and responding to patient risk

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

The service had policies so that staff knew how to respond promptly to any sudden deterioration in a patient's health for both children and adults. This policy had been shared with all staff and was also available electronically so that any staff member could access it whenever they needed to.

Staff undertook a risk assessment of each patient prior to carrying out treatment. This included name, date of birth, site of stone and whether the patient may be pregnant. During the inspection we observed this assessment take place in 3 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 as urine infection screening outcomes, pain levels and follow up information.

The service had implemented a safety checklist for use before each procedure, these included checks for identity and affected side for treatment.

Staff had access to the picture archiving communications system (PACS), and the urologist would review any anomalies in images.

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. Managers regularly reviewed and adjusted staffing levels and skill mix in line with operational demands.

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. Managers reviewed the register to ensure staff were registered.

Due to the specialist nature of the service, managers did not use bank and agency staff.

Diagnostic imaging

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

Staff turnover was low within the service, all clinical members of staff had been employed for longer than 5 years.

The service had low vacancy rates with only one vacancy at the time of inspection that was in the process for recruitment.

Records

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

Patient notes were comprehensive, a treatment record for each patient was handwritten by the radiographer. We reviewed 10 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.

When patients transferred to a new team, there were no delays in staff accessing their records as they were then shared with the host organisation whilst a carbon copy was kept at the base of the service.

Managers audited records; we reviewed the 3 months of audit checks which demonstrated that managers responded to outliers identified in these.

Records were stored securely.

Incidents

The service managed patient safety incidents well. Staff recognised incidents and near misses and knew how to report them.

Since the previous inspection the service now had a process in place for the reporting of incidents and staff knew what incidents to report and how to report them.

The service had no reported never events and had one reported incident between March 2022 and February 2023. We reviewed the documentation for this incident which demonstrated that the incident had been investigated in collaboration with the host organisation.

Staff understood and could explain the duty of candour.

Is the service effective?

Inspected but not rated 

We do not currently rate the effective domain for diagnostic services.

Diagnostic imaging

Evidence-based care and treatment

The service provided care and treatment based on national guidance and evidence-based practice. Managers checked to make sure staff followed guidance.

Staff followed up-to-date policies to plan and deliver high quality care according to best practice and national guidance.

Managers audited radiation doses to monitor patients' exposure to ionising radiation to ensure these were as low as reasonably practicable in line with the Ionising Radiation (Medical Exposures) regulations 2017.

All clinical staff had completed refresher training on radiation safety and protection.

Nutrition and hydration

Nutrition and hydration need 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 and 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 visual analogue scale (VAS). VAS is a picture chart to indicate levels of pain and is also suitable for patients unable to verbally communicate their level of pain. We observed staff undertaking this assessment during our inspection.

The host organisations staff administered the pre-procedure analgesia.

Patient outcomes

Staff monitored the effectiveness of care and treatment. They used the findings to make improvements and achieved good outcomes for patients.

Did not attend rates were monitored and recorded meaning that the service could produce a data report for the host hospitals to demonstrate efficiencies, so that they could make best use of the lists for patients awaiting this treatment.

Patient feedback was now being obtained at some of the locations with plans to extend this to all locations where services were provided. Leaflets were offered to patients so that feedback could be captured.

At the time of the inspection formal meetings with the host trusts, to discuss patient outcomes, had not been set but they had plans to address this supported by NHS England.

Managers had a programme of repeated audits to check improvement over time. These included hand hygiene, driver and equipment, clinical assessment, treatment record and consent audits.

Competent staff

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

Diagnostic imaging

Staff were experienced, qualified and had the right skills and knowledge 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.

Managers supported staff to develop through yearly, constructive appraisals of their work and radiographer staff to develop through yearly clinical supervision of their work. The service was in the process of undertaking appraisals for all staff at the time of inspection and we saw that these had been arranged.

Managers sent learning materials with monthly newsletters for staff to use for continuous professional development.

Multidisciplinary working

Doctors, nurses and other healthcare professionals worked together as a team to benefit patients. They supported each other to provide good care.

Staff took part in safety huddles at the beginning of each paediatric case.

Leaders said they had good working relationships with hospital clinicians of all grades across their locations and we observed several testimonials evidencing this.

Staff of different roles worked together as a team at the location we inspected, to benefit patients and ensure efficiency of the service.

Seven-day services

Key services were available to support timely patient care.

Staff could call for support from doctors and other disciplines. 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.

Consent, Mental Capacity Act and Deprivation of Liberty Safeguards

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

The service had a consent policy that was up-to-date and referred to relevant guidance.

Staff understood how and when to assess whether a patient had the capacity to make decisions about their care and could give examples of this.

Diagnostic imaging

Staff gained consent from patients for their care and treatment in line with legislation and guidance and clearly recorded this. We reviewed 10 patient records and found consent was recorded on each of them.

Managers monitored compliance with the services consent policy, we viewed 3 months of records audits that demonstrated consent was gained and recorded in the majority of cases. Managers had responded to the outliers identified in this audit and had implemented a new care record document with a dedicated section to record consent and a reminder was sent to staff as part of the monthly newsletter.

Clinical staff received and kept up to date with training in the Mental Capacity Act and Deprivation of Liberty Safeguards as it was part of their mandatory training programme. Staff could give examples of times when they had assessed a patient did not have the capacity to consent to the procedure and what they would do in these circumstances.

Is the service caring?

Good 

Our rating of caring stayed the same. 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 took time to interact with patients and those close to them in a respectful and considerate way. Staff introduced themselves and those present for the procedure to patients when they arrived.

Patients said staff treated them well and always maintained their privacy and dignity during their visit.

Emotional support

Staff provided emotional support to patients to minimise their distress. They understood patients' personal needs.

Staff gave patients and those close to them help, emotional support and encouragement when they needed it. We observed staff assisting patients on and off the procedure table to prevent them from injuring themselves and taking the time to talk to patients about things which were important to them other than the treatment they were undergoing.

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 and could explain in detail methods they used to address patients' anxieties.

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.

Staff supported patients to make informed decisions about their care by explaining the treatment in a way they could understand and by giving patient's the opportunity to ask questions.

Diagnostic imaging

Patients gave positive feedback about the service. We spoke with 3 patients on our inspection, all gave positive feedback about the service and their treatment with 1 expressing their experience had been “excellent and staff were really nice”.

We reviewed results of patient feedback questionnaires which showed a 100% satisfaction rate in the 2 locations these were carried out.

Patients and their families could not always give feedback on the service and their treatment, but the service had plans to extend the feedback leaflets to all locations in the future.

Is the service responsive?

Good 

Our rating of responsive stayed the same. 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.

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.

Facilities and premises were appropriate for the services being delivered. At the location we inspected the environment was fit for purpose and resources were available if required.

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.

The service had information leaflets available in the Welsh language which was spoken by the patients and some of the local community. The service did not have any other languages available.

Host organisations were responsible for arranging interpreters or signers when needed, staff told us that the procedure would not be carried out if they did not have an interpreter present for patients who required one.

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.

Diagnostic imaging

The service did not collect or monitor referral to treatment times as the host organisation managed the booking of patients due to undergo Lithotripsy treatment by the service.

The service monitored cancelled and missed appointments by patients and managers worked with the host organisations by auditing these to keep the number of cancelled treatments to a minimum.

Between January 2022 and January 2023, the service had not cancelled any appointments or clinics.

Learning from complaints and concerns

The service treated concerns and complaints seriously, investigated them and shared lessons learned with all staff. It was not always easy for people to give feedback and raise concerns about care received.

The service received complaints via the host organisations. Patients would contact the host organisation with complaints about the service which would then be handed to the provider for investigation and a response.

Patients could also make a complaint through the providers website.

At the time of our inspection the service had received one complaint. We observed that the investigation into this complaint was completed in conjunction with the host hospital and highlighted primarily communication concerns of which managers sought action to rectify.

Staff told us that information and learning from complaints was shared with them.

Staff understood the policy on complaints and could explain to us how they would deal with them.

Is the service well-led?

Our rating of well-led improved. We rated it as good.

Leadership

Leaders had the skills and abilities to run the service. They understood and managed the priorities and issues the service faced. They were visible and approachable in the service for patients and staff, and managers supported staff to develop their skills.

Leaders had the skills, knowledge, experience, and integrity that they needed to run the service; all were radiographers with experience of lithotripsy. Leaders had shown integrity throughout the improvement processes prompted by previous inspections, being transparent about areas for improvement with staff and external bodies.

The directors had understood, managed, and acted on the priorities and issues the service faced following the warning notice from our previous inspections. New policies and procedures had been implemented to keep people safe and they had processes in place to ensure that all staff had the skills and knowledge to carry out their roles effectively and safely

Diagnostic imaging

Staff we spoke to said that leaders were approachable and supportive and felt that the service had improved. Managers clinically practiced regularly and were visible and accessible to staff members.

Since the previous inspections the service had taken a proactive approach in obtaining the signed agreements by repeated telephone calls and emails to relevant contacts within the NHS trusts and were also working closely with NHS England and Improvement to resolve the outstanding unreturned agreements.

The service had implemented a practicing privileges agreement and leaders could show that work was ongoing to secure responses from each of the host organisations.

The service had appropriate indemnity insurance in place.

Vision and Strategy

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

At the time of this inspection leaders said that they wanted to provide safe and effective treatment for a wide range of health problems.

Following this inspection, the service provided us with a vision and strategy statement document which outlined their overall vision for the company and what actions they were taking to achieve this.

Culture

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

Staff felt supported and were proud of the work they carried out in the service and of the improvement work that had taken place in response to the previous inspections.

The culture of the organisation was centred on improving the service and the needs and experience of the people who used it.

Staff said that they felt able to raise concerns without fear of retribution and knew how to do this within the service and the host organisations they worked with.

Governance

Leaders operated effective governance processes, throughout the service and with partner organisations. Staff at all levels were clear about their roles and accountabilities and had regular opportunities to meet, discuss and learn from the performance of the service.

The service had a governance structure with a governance policy, structure chart and regular board meetings. Review of the most recent board meeting minutes showed discussions around key topics such as contracts, quality improvement work and radiation safety.

Leaders were clear about their roles and had designated responsibilities. The introduction of the on-call director rota and policy provided a clear designated leader for staff to contact each week. The policy listed all the duties of which they were required to do and were accountable for.

Diagnostic imaging

Management of risk, issues, and performance

Leaders and teams used systems to manage performance effectively. They identified and escalated relevant risks and issues and identified actions to reduce their impact. They had plans to cope with unexpected events.

The service had individual hospital risk assessments which had been completed in conjunction with the radiation protection advisor and general risk assessments such as lone working had been reviewed.

The service monitored performance through audits such as hand hygiene, clinical assessment, and care records audits. The results from these audits were discussed in the senior leader's governance meetings.

At the time of this inspection the service had not yet created a risk register to grade and monitor service risks due to the focus of work in other areas such as safeguarding training, patient safety policies and service level agreements. However, this did feature as part of their ongoing improvement action plan.

Information Management

The service collected reliable data and analysed it. Staff could find the data they needed, in easily accessible formats, to understand performance, make decisions and improvements. The information systems were integrated and secure. Data or notifications were consistently submitted to external organisations as required.

The service had arrangements for the confidentiality of patient identifiable data, records and data management systems in line with the General Data Protection Regulation.

The service collected data through various means such as care records, session audit records and incident and fault logs.

Engagement

Leaders engaged with patients, staff, the public and external stakeholders to plan and manage services. They collaborated with partner organisations to help improve services for patients.

Staff told us that they had conducted their first meeting as part of the new governance system and leaders told us that this was to continue on a regular basis to share updates with the team.

The service engaged with organisations and shared the data they collected about session lists so that these could be maximised. The service also provided a document to the host organisations with advice on how to assist with efficiency of lists.

Since our initial inspection in 2022 leaders had been collaborating with NHS England to make improvements to the service and told us that this partnership work had been invaluable. They had worked with NHS England to develop governance, safety, and auditing processes within the service and to help create a standard NHS organisation contract template.

The service engaged with the public through social media platforms and through charity sponsorships and events.

Diagnostic imaging

Learning, continuous improvement and innovation

All staff were committed to continually learning and improving services. Leaders encouraged innovation and participation in research.

There was a strong focus on continuous learning and improvement throughout the organisation, including through external accreditation and participation in research.

The service had achieved the ISO 9001:2015 Quality Management System Standard accreditation, which meant it had demonstrated the ability to monitor and manage quality across the organisation in accordance with these standards.

One of the directors was undertaking a PHD researching further clinical applications of shock wave lithotripsy and was a board member of the International Alliance of Urolithiasis where they have contributed to the research for the development of international guidelines.

The service was undergoing research in collaboration with an NHS hospital into the use of this therapy for the treatment of diabetic ulcers.