

Focus Medical Services Limited

Quality Report

Buckland House 2
Park 5 Business Centre
Harrier Way
Sowton Industrial Estate
Exeter
Devon
EX2 7HU

Tel: 01392 360 502

Website: <http://www.focusmedical.co.uk/>

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

Ratings

Overall rating for this location

Requires improvement



Are services safe?

Requires improvement



Are services effective?

Are services caring?

Good



Are services responsive?

Good



Are services well-led?

Requires improvement



Mental Health Act responsibilities and Mental Capacity Act and Deprivation of Liberty Safeguards

We include our assessment of the provider's compliance with the Mental Capacity Act and, where relevant, Mental Health Act in our overall inspection of the service.

Summary of findings

We do not give a rating for Mental Capacity Act or Mental Health Act, however we do use our findings to determine the overall rating for the service.

Further information about findings in relation to the Mental Capacity Act and Mental Health Act can be found later in this report.

Summary of findings

Letter from the Chief Inspector of Hospitals

Focus Medical Services (FMS) is operated by Focus Medical Services LTD. The service has seven lithotripsy units, which comprise of a lithotripter, ultrasound machine, mobile image intensifier and treatment table.

Focus Medical Services provides a mobile Extracorporeal Shock Wave Lithotripsy (ESWL) service to hospitals throughout the UK and Republic of Ireland. Lithotripsy is a treatment using electromagnetic shock waves, by which a kidney stone or other calculus is broken into small particles that can be passed out by the body. ESWL is a non-invasive procedure.

The head office is based in Exeter where one of the directors and an office administrator are based. The service provides treatment to adults most but do occasionally also treat children.

From September 2018 to August 2019, the service carried out 5,819 lithotripsy treatments for adults and seven treatments for peyronies (inside scarring of the penis) in England. In the same period, the service treated 17 children between the ages of one and 17 years of age.

We inspected this service using our comprehensive inspection methodology. We carried out the inspection with a short announced part of the inspection on 22 to 25 September and 1 October 2019.

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

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

We rated it as **Requires improvement** overall.

We found areas of practice that require improvement:

- There was no training policy providing guidance to staff about when mandatory training needed to be completed to support safe practice.
- Staff received adult safeguarding training but did not receive any child protection training. There was a safeguarding adults policy but there was no child safeguarding policy providing guidance for staff if they had concerns about children's safety.
- There was an inconsistent use of infection control measures to protect patients, themselves and others from infection.
- Equipment was mostly maintained but some equipment had not been serviced to ensure their safety.
- There was no lone worker policy for staff required to work on their own.
- Decisions to justify radiation were not clearly documented. The service did not check if referrals for lithotripsy was in accordance with care and treatment based on national guidance and evidence-based practice.
- Staff did not have access to picture archiving and communication systems in NHS locations where they delivered lithotripsy. They used NHS employed staff's access to log in.
- There were systems to report an incident, but these were not always clear. There was no incident reporting policy to provide guidance and consistency of reporting. Staff recognised and reported incidents. Managers investigated incidents and shared lessons learned with the whole team.

Summary of findings

- The service carried out radiation exposure audits, but it was not clear how the results were used to ensure/improve patient safety.
- There was no specific policy, guidance or protocols relating to treatment of kidney stones in children.
- The service did not monitor the effectiveness of care and treatment.
- Additional radiation training was not given to operating department practitioners who occasionally had to use image intensifiers to carry out procedures. Staff did not receive formal training in the use of ultrasound to locate kidney stones.
- The service did not have a formal vision or strategy but aims and progression of the company were discussed informally with staff during appraisals.
- Governance structures needed to be strengthened. There was insufficient oversight of performance and audits.
- The service collected reliable data but did not analyse this to identify where service improvements could be made.

However:

- Staff completed and updated risk assessments for each patient and removed or minimised risks.
- The service had enough staff with the right skills and experience to keep patients safe from avoidable harm and to provide the right care and treatment.
- Staff kept detailed records of patients' care and treatment. Records were clear, up-to-date, stored securely.
- Staff assessed and monitored patients during procedures to see if they were in pain.
- Managers appraised staff's work performance and held supervision meetings with them to provide support and development.
- Staff worked alongside medical and nursing staff from the hosting NHS locations. They supported each other to provide good care.
- Staff confirmed consent had been sought before carrying out lithotripsy procedures.
- Staff treated patients with compassion and kindness, respected their privacy and dignity, and took account of their individual needs. Staff provided emotional support to patients and made sure patients understood their care and treatment.
- The service planned and provided care in a way that met the needs of local people and the communities it served.
- The service was inclusive and took account of patients' individual needs and preferences. Staff made reasonable adjustments to help patients access services. People were booked to attend pre-booked sessions delivered by the provider and received the right care.
- The service treated concerns and complaints seriously, investigated them and shared lessons learned with all staff.
- Leaders had the integrity, 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 staff. They supported staff to develop their skills and take on more senior roles.
- Staff felt respected, supported and valued. They were focused on the needs of patients receiving care.
- Directors identified and escalated relevant risks and issues and identified actions to reduce their impact.

Summary of findings

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

Nigel Acheson

Deputy Chief Inspector of Hospitals (South)

Summary of findings

Our judgements about each of the main services

Service	Rating	Summary of each main service
Diagnostic imaging	Requires improvement 	Start here...



Summary of findings

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Requires improvement 

Focus Medical Services

Services we looked at:

Diagnostic imaging

Summary of this inspection

Background to Focus Medical Services Limited

Focus Medical Services is operated by Focus Medical Services LTD. The service opened in 1999. It is a private service operating from a head office based in Exeter. The service primarily serves the communities throughout the UK and Republic of Ireland.

The service is registered to provide the following regulated activities:

- Diagnostic and screening procedure

- Treatment of disease, disorder and injury.

During the inspection, we visited lithotripsy treatments carried out in NHS hospitals in Cheltenham, Plymouth and Winchester.

The provider has had a registered manager in post since November 2011.

Our inspection team

The team inspecting the service comprised a CQC lead inspector, one other CQC inspector, and a specialist

advisor with expertise in radiography. The inspection team was overseen by an Inspection Manager and Amanda Williams, Interim Head of Hospital Inspection (South).

Information about Focus Medical Services Limited

The main treatment provided by this provider was lithotripsy (kidney stone treatment), the equipment was also used to treat conditions such as tennis elbow, plantar fasciitis (heel pain) and peyronies disease (inside scarring of the penis).

There was a clear patient journey pathway which set out the part of the patient journey the service was responsible for. This demonstrates the service was only responsible for the treatment they carry out and not patient related responsibilities before and after treatment. The service has eight vehicles used to transport the equipment to NHS locations where treatment was carried out.

We spoke with seven staff including radiographers, operating department practitioners and directors of the company. We observed 21 treatments being carried out and spoke with four patients. During our inspection, we reviewed 21 patient records.

There were no special reviews or investigations of the provider ongoing by the Care Quality Commission at any

time during the 12 months prior to this inspection. The service was last inspected in September 2013, which found the service met all standards of quality and safety it was inspected against.

Activity (September 2018 to August 2019)

- In the reporting period 1 September 2018 to 31 August 2019, the service carried out 9,684 treatments in total. Of these, 5,826 treatments were carried out in England. In the same period, the service treated 17 children and young people in England.

There were 13 mobile lithotripsy technicians (nine radiographers and four operating department practitioners), one engineer, one office administrator and three directors. Two of the directors could also work as lithotripsy technicians.

Track record on safety

- No never events
- Two clinical incidents causing low harm to patients
- No serious injuries

Summary of this inspection

The company had received no complaints in the 12 months prior to our inspection.

Services accredited by a national body:

The service did not hold any national accreditation. This was because there was no national lithotripsy accreditation available.

Services provided at the hospital under service level agreement:

- Radiation protection advisory and medical physics services.
- IT systems and services.
- External training.

Summary of this inspection

The five questions we ask about services and what we found

We always ask the following five questions of services.

Are services safe?

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

- There was no training policy setting out expectations of completion of mandatory and statutory training.
- There was a safeguarding policy for adults (2018) but there was no child safeguarding policy providing guidance for staff.
- There was an inconsistent approach to hand hygiene and equipment was not always cleaned between patients.
- Equipment was not always regularly maintained in accordance with manufacturer guidelines.
- There was some ageing equipment as five pieces of equipment were more than 12 years old.
- The design of the environment was not always in adherence with national guidance as not all NHS locations had a warning light outside the room to warn people that radiation was in progress.
- Staff carried out daily safety checks of specialist equipment on the days we inspected the service. However, it was difficult to gain an overview of when and if these were always completed on all of the days the equipment was used. This was because equipment was used in different locations.
- There was no standard operating procedure to provide guidance to staff to summon help in the event a clinical emergency of patients under their care.
- The rationale to justify the use of x-ray during treatment sessions for individual patients, was not always documented accurately.
- The service audited exposure time when treatment was carried out using x-ray and if this exceeded the alert levels set by the radiation protection advisor. However, it was not clear how this information was used to improve services and there were no national standards to benchmark against.
- Staff did not have direct access to NHS hospital picture archiving and communication system (PACS) but used NHS hospital staff login details to access this information.
- There was no incident reporting policy to provide guidance for all staff including definitions of incidents and near misses they should be reporting. External regulators were not always informed of incidents relating to radiation.

However:

- Staff had an awareness of how to protect patients from abuse.

Requires improvement



Summary of this inspection

- There was a procedure staff followed when equipment was faulty.
- All company vehicles were serviced regularly including safety testing of tail-lifts, which were serviced every six months in line with Lifting Operations and Lifting Equipment Regulations (LOLER, 1998).
- The service had enough suitable equipment to help them to safely care for patients.
- Staff completed and updated risk assessments for each patient and removed or minimised risks.
- Checks were completed to make sure the right patient attended for treatment.
- 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.
- 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.
- Staff knew what incidents to report and how to report them and the directors felt there was a good reporting culture among staff.

Are services effective?

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

- The service did not monitor referrals to ensure these were in line with national guidance such as National Institute for Health and Care Excellence: Renal and ureteric stones: assessment and management, 2019.
- The service did not monitor the effectiveness of care and treatment. The service carried out annual audits of patient treatments but only had access to a small part of the patients' journey. As a result, the service did not know the outcome of a patients' treatment.
- The completed competency framework was kept by the individual staff and the service did not keep any copies of this. This meant the service was unable to demonstrate all staff had completed their competency framework.
- Operating department practitioners (ODPs) received the same induction as radiographers. However, they did not receive additional radiation protection training to ensure they had up-to-date knowledge of radiation risks and associated regulations.
- Staff did not receive formal training in the use of ultrasound to locate kidney stones. Training was given under supervision as part of the induction training.

Summary of this inspection

- There was a separate assessment framework, which was intended to assess staff's ongoing competence. However, this was not used as it was designed to and did not evidence staff's competency was regularly reviewed and assessed.

However:

- The service was unable to participate in national clinical audits. This was because there were not national audits they could submit data to and benchmark against.
- Staff recorded and monitored diagnostic reference levels (DRLs) to ensure these met as low as reasonable required radiation dosages for the procedures they carried out.
- Staff had access to local rules for lithotripsy.
- Staff assessed and monitored patients during procedures to see if they were in pain.
- Managers gave all new staff a full induction tailored to their role before they started work. Directors supported staff to develop through yearly appraisals of their work.
- Staff worked alongside medical and nursing staff from the hosting NHS locations. They supported each other to provide good care.
- Staff confirmed consent had been sought for the procedure.

Are services caring?

We rated it as **Good** because:

- 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 and those close to them in a respectful and considerate way.
- Patients said staff treated them well and with kindness.
- Staff provided emotional support to patients.
- Staff understood the impact a patient's care, treatment or condition had on their wellbeing and on their relatives, both emotionally and socially.
- Staff made sure patients understood their care and treatment.
- Staff talked with patients, families and carers in a way they could understand.
- Patients could give feedback on the service and their treatment and staff supported them to do this. Feedback showed patients were treated with dignity and respect.

Good



Are services responsive?

We rated it as **Good** because:

Good



Summary of this inspection

- 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.
- The service was flexible to accommodate additional service delivery requests from the hosting NHS locations.
- The service was able to adapt treatment techniques to take account of any special needs patients may have.
- The service had not received any complaints in the period between 25 July 2018 and 24 July 2019. However, there were processes to ensure complaints were dealt with in a timely manner in accordance with their complaints policy.

Are services well-led?

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

- The service did not have a formal vision or strategy but aims and progression of the company were discussed informally and with staff during appraisals.
- There was a clear set of values for the service, although not all staff were able to recall these.
- The service did not report workforce equality standards data in line with the national NHS standard contract.
- Governance structures needed to be strengthened. There was limited scrutiny of performance and auditing of processes to provide sufficient oversight and assurance of the services provided.
- There were also a number of key policy/procedures which were not in place to direct and support staff practice, such as child protection policy, no incident reporting policy, no lone working policy and no policy re kidney stones in children.
- The service did not have regular formal meetings with the radiation protection advisor and medical physics in line with Ionising Radiation (Medical Exposure) Regulations, 2017.
- There was a lack of clarity of responsibility for patient safety. There were no regular or annual meetings to review the contracts and discuss performance with NHS providers to review contracts.
- The service collected reliable data but did not analyse this to identify where service improvements could be made.

However:

- Leaders had the integrity, 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 staff. They supported staff to develop their skills and take on more senior roles.

Requires improvement



Summary of this inspection

- There was a clear company structure which showed different people's responsibility.
- Staff felt respected, supported and valued. They were focused on the needs of patients receiving care.
- Staff felt their wellbeing was looked after by Focus Medical Services.
- Staff described the culture of the service as supportive and having a 'team mindset.'
- Staff felt the culture of the service was 'open' and 'friendly' and they would feel confident to raise any concerns with the directors.
- Directors identified and escalated relevant risks and issues and identified actions to reduce their impact.
- The services monitored patient feedback but did not use the information to improve services.

Detailed findings from this inspection

Overview of ratings

Our ratings for this location are:

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

Diagnostic imaging

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

Are diagnostic imaging services safe?

Requires improvement 

Mandatory training

The service provided mandatory training in key skills to all staff. Training was not provided annually but directors monitored when staff were required to update their training.

The contents of mandatory training met the needs of patients and staff. Staff spoke positively about the quality of mandatory training they received. They told us the most recent manual handling training session (February 2018) had been tailored to their needs. The trainer used the equipment they worked with on a daily basis as the focus of the training which they had found useful.

However, not all staff were clear about what courses were included as part of mandatory training and they were not always sure about how often they should complete some of the training. There was no training policy to guide staff about training they were required to complete and how often regular updates should be undertaken. There were no formal completion targets.

Staff received mandatory training when they were required to. Training compliance documents demonstrated that 93-100% of staff had received mandatory training between 2016 and 2019. Training was not always delivered annually. For example, Emergency First Aid at Work training was last delivered in February 2017 and was only delivered every three years by an external company. Radiation safety and protection training was last delivered in March 2016 and was delivered every three to five years. There was a plan to

deliver this training again in 2020. Staff received manual handling training in 2018, which included loading and unloading of equipment. Staff were up to date with the mandatory e-learning which had been completed by all staff within the last 12 months. This mandatory e-learning training was completed every three years and included: slips, trips and falls, safeguarding adults, infection prevention and control (clinical), moving and handling (clinical), equality, diversity and human rights, dignity in care and conflict resolution. Managers monitored mandatory training and alerted staff when they needed to update their training.

Mandatory training was planned in advance to make sure all staff working for the service, despite being geographically spread, could attend. This was planned to coincide with an annual meeting which all staff attended and accommodation was provided at a central location.

Safeguarding

Staff had an awareness of how to protect patients from abuse. Staff received adult safeguarding training but did not receive any child protection training.

Staff were aware of how to identify adults at risk of, or suffering, significant harm and worked with other agencies to protect them but stated they had never had to raise any formal concerns. There was a safeguarding adults policy providing guidance for staff of who to inform and how to raise a safeguarding concern about adults. However, there was not a child protection policy providing staff with guidance and information about actions to take if they had child protection concerns. Staff told us they would inform NHS staff they worked alongside if they had concerns about patients

Diagnostic imaging

Staff completed a safeguarding vulnerable adult e-learning module, but staff were unsure about which level of safeguarding training they completed. One of the directors were the named lead for children and adult safeguarding but they had not received any specific training at the recommended level to act as the safeguarding lead as stated in Intercollegiate document: Adult Safeguarding: Roles and Competencies for Health Care Staff, 2018.

Staff did not receive any training on child protection in accordance with national guidance: Safeguarding children and young people: roles and competences for health care staff (intercollegiate document), 2014. The service had treated some children at locations in Leeds and Leicester. The treatment was carried out under supervision from NHS employed staff. Those staff we spoke with stated they would raise any concerns they had with the NHS based staff.

The provider was unclear about what responsibility Focus Medical Services (FMS) staff had with regards to safeguarding concerns. Staff told us they would raise the concern with either the nurse or consultant they were working with for that particular clinic. Some staff also told us they would also inform their senior manager of any safeguarding concerns they had. There was no local standard operating procedure or policy for staff to follow if they identified a safeguarding concern when they worked at different NHS trusts.

Patients could ask for chaperone, but it was not offered routinely. Patients were not required to undress for the treatment but to expose the lower back/kidney area. If patients asked for a chaperone, this would be provided by NHS employed staff from the hosting NHS location if the FMS staff were both of the same gender.

Records of disclosure and barring service (DBS) checks were maintained by the service. This included the DBS reference number for each member of staff and the date the DBS check was completed and when it was due for renewal.

Cleanliness, infection control and hygiene

Most staff mostly used control measures to protect patients, themselves and others from infection. However, not all staff complied with hand hygiene national standards and staff did not always clean equipment in accordance with their policy.

Procedure rooms were visibly clean and had suitable furnishings which were clean and well-maintained. One of the locations we visited was small and cluttered which made effective cleaning difficult. The service did not obtain any information or audit results about cleanliness of the procedure rooms they used to provide treatment and could therefore not be assured how often the rooms were cleaned.

Staff followed infection control principles such as handwashing inconsistently. Staff did not always follow national guidance (National Institute for Health and Care Excellence (QS61, 2014) and the provider's Infection Control Policy (2018). The policy stated, 'hands should be decontaminated immediately before each and every direct episode of patient care or contact.' We observed that this did not always happen, some staff washed their hands at the start of a new episode of care and some washed their hands after treatment had occurred but not all staff adhered to this guidance. We did not see staff use alcohol-based hand gel consistently. The service did not audit hand hygiene compliance.

The application of ultrasound gel did not follow the services infection control policy. Ultrasound gel is used to transmit ultrasound waves effectively. The policy stated ultrasound gel should be 'dispensed directly from the container onto a paper towel and then applied onto the patient.' We observed staff dispensing the gel directly onto the patient's skin, with the container at times making direct contact with the patient's skin and was not cleaned between patient use.

Staff mostly cleaned equipment after patient contact. Staff cleaned the patient trolley and the lithotripter with wipes designed for decontamination of medical equipment between patients. However, not all staff cleaned the trolley each time although the sheet was changed between each patient. The service did not audit compliance with their policy in relation to cleaning of equipment between patients.

Staff had access to an Infection Control policy. A paper copy of the policy was available in the information files

Diagnostic imaging

for each set of equipment that we observed. The policy was issued in October 2018, but the document did not identify a date for when the policy required a review. The policy did not contain any references to ensure the information was based on evidence base guidance to develop the policy.

Control of substances hazardous to health (COSHH) assessments were carried out but not reviewed in line with the COSHH policy (April 2018). We reviewed two COSHH risk assessments for the use of ultrasound gel and silicone oil. Both risk assessments contained limited information and detail. Only the ultrasound gel risk assessment identified a completed date of October 2018. There was no completion date on the silicone oil risk assessment. Neither risk assessments had identified a date for a review, despite the policy stating a review should be completed every six months. Therefore, the ultrasound gel risk assessment was overdue for a review by 11 months.

If patients had known communicable disease, these patients would be seen last and the equipment and room cleaning afterwards to minimise the risk of cross infection.

There had been no reported incidents relating to the prevention and control of infections in the 12 months prior to our inspection.

Environment and equipment

The design of the environment was not always in adherence with the national guidance as not all locations had a warning light outside the room to warn people radiation was in progress. Equipment was mostly serviced regularly, and staff were trained to use them. There were systems to ensure daily quality assessment and calibration of equipment was carried out, but these did provide sufficient oversight.

Equipment was not regularly maintained in accordance with manufacturer guidelines. An electronic maintenance log was maintained for each piece of equipment which demonstrated preventative maintenance, annual radiation testing and equipment faults. Four pieces of

equipment had not been serviced within the last 12 months. However, these had just exceeded the 12-month service due date as they were last serviced in August and September 2018.

Records demonstrated that equipment had been portable appliance tested (PAT) between January and November 2018 and of these seven pieces of equipment were last tested more than 12 months ago. The law does not specify how often electrical equipment should be tested. It is the responsibility of the provider to decide what level of maintenance is needed according to the risk of an item becoming faulty.

There was a procedure staff followed when equipment was faulty. Staff called the services engineer for support. The engineer would try to support staff over the telephone, however, if this did not work, the engineer would come out to the clinic location and would bring a replacement piece of equipment. This made sure the clinic could still go ahead. Staff told us they would also call the senior management team to inform them of the equipment issues they were having and the action they had taken.

There was some ageing equipment as five pieces of equipment were more than 12 years old. There were three lithotripters and two image intensifiers which had been operational more than 12 years and had been operating for more than 12,000 hours as recorded on their maintenance log. The service had obtained reassurance from the manufacturers that spare parts would be available for at least a further five years. There was a replacement programme which included recent purchase of five upgraded ultrasound machines and four new treatment beds to a heavier capacity model.

All company vehicles were serviced regularly including safety testing of tail-lifts, which were serviced every six months in line with Lifting Operations and Lifting Equipment Regulations (LOLER, 1998). Records were held to demonstrate maintenance and servicing of all vehicles. The services had eight vans and 14 support vehicles which staff could use to travel to different locations to provide the service. We reviewed service records for each vehicle and found these were compliant with annual servicing/MOT, insurance and road tax. The service had a contract with a national automobile service to response

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to any vehicle breakdowns which may occur. They also had urgent access to tail lift repair from an external company who would attend immediately if required. Each van was fitted with extensive security alarms.

There was a standard operating procedure to support staff in loading and unloading the equipment required to provide treatment sessions for patients, from the company van. We saw staff following this procedure when loading the van and saw how equipment was bolted down so that it did not move or get damaged in transit.

The design of the environment was not always in adherence with the national guidance service's local rules as not all locations had a warning light outside the room to warn people radiation was in progress. This was not in adherence with the Department of Health Building Notes (HBN 6, 2001). This guidance states there must be "Controlled Area" and "X-ray on" warning lights over the door. There was a lack of processes for daily checks of the environment to be carried out to provide assurance of a safe environment to provide treatment. There were signs in both words and pictures informing people about areas or rooms where radiation exposure took place. There was a sign on the door to show if the x-ray machine was in use. We noticed at one location we visited the sign remained in the position showing x-ray was in use all day despite this not being the case with all treatment sessions. This sign did not light up to display that x-ray was in use, nor did the door automatically lock. There was only a sign on the door asking people to knock before entering. This alone would not protect people from radiation if they were to enter the room without knocking when x-ray was in use. There were not always warning lights displayed outside of the room where radiation was performed. We saw staff walk in and out of the room without always knowing if radiation was performed at the time. This meant there was a risk of staff entering the room when radiation was being performed. This was not outlined in the generic local rules and staff were not aware if this had been discussed with the hosting NHS location. Procedures rooms were lead lined to prevent unintentional radiation to other staff or persons in the vicinity of the procedure room.

Staff carried out daily safety checks of specialist equipment on the days we inspected the service. However, it was difficult to gain an overview of when and if these were always completed on the days the

equipment was used as equipment was used in different locations and not as part of 'one set' of equipment. Staff completed a daily checklist for cleaning of equipment and a separate log for calibration of a copper testing for the image intensifier (an electronic device that converts the X-ray beam intensity pattern into a visible image suitable to be displayed on a monitor). For example, we noted the cleaning log for equipment used in Cheltenham on 22 September 2019 had been completed on 30 days between 1 May and 27 August 2019. The copper plate testing had been carried out 16 days in the same period. However, equipment was not always used in the same locations as sometimes this was changed over between different vans or called back for servicing. The daily equipment log referred to equipment labelled one to eight but there were more than eight pieces of equipment. The service did not audit if these checks were carried out daily and we were therefore not assured there was sufficient oversight of daily cleaning and quality testing of equipment used.

Staff carried out a daily testing of the image intensifier but did not always do this as instructed. Staff tested 'kV' (kilovolt), which was consistently above the reference range on one record we reviewed. We observed staff carried out the test without moving the trolley out of the way as stated on the guidance document. Although the KV was outside of range we could not see if staff had reported this (apart from one day) or that actions had been taken to test the equipment further.

Staff calibrated the image intensifier and the lithotripter each morning as part of the daily checks. This was to ensure they were aligned to within one millimetre so that kidney/renal stones could be targeted effectively. The service monitored how many treatments were carried out by each piece of equipment including the coils used to deliver shockwaves in the lithotripter. Records demonstrated the coils had all been replaced between September 2016 and September 2019. Directors provided assurance that the coils/power did degenerate over time which meant the age and the number of treatments did not impact on the quality of the treatment. When coils had reached the end of their life they simply 'blew' and were replaced.

The service had a service level agreement (SLA) with an NHS hospital to provide quality assessment testing and

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radiation assessments for the image intensifier. The SLA also included the provision of radiation protection advisor to support staff with any queries or concerns related to radiation.

The service had enough suitable equipment to help them to safely care for patients. The service employed an engineer who was responsible for the maintenance of medical equipment. The service had additional equipment and vehicles to ensure equipment could be taken out of the schedule to allow for maintenance work to be carried out without impacting of the scheduled lithotripsy services. If equipment broke down, staff contacted the engineer who could bring replacement equipment which was stored in a central storage facility based in the Midlands. It meant that sometimes treatments were delayed or rescheduled.

Staff had access to lead aprons and thyroid collars (lead lined collars to protect the thyroid) for radiation protection, which were checked annually for damage, wear and tear. Lead aprons were part of the equipment kit brought to each location where treatment sessions were provided. Lead aprons were last checked between 10 and 22 August 2018 and meant the annual check was overdue by one month at the time of our inspection.

Staff disposed of waste safely. Staff segregated waste and disposed of this in designated waste bins.

Assessing and responding to patient risk

Staff completed and updated risk assessments for each patient and removed or minimised risks. Staff used a pre-safety checklist or utilised the NHS Surgical Safety Checklist based on the World Health Organisation (WHO) surgical safety checklist, these had been adapted to specifically highlight risks associated with lithotripsy. The service introduced a 'pre-treatment safety checklist' in 2015 for use in hospitals where a WHO checklist was not produced. The check list included marking the right or left hand indicating which kidney or ureter was being treated. However, the service did not audit compliance with pre-treatment safety checklist to ensure this was always completed to reduce patient safety risks.

Risks were assessed when patients arrived for their treatment. The responsibility to carry out risk assessments for each patient lay with the hosting NHS hospital. The information was then checked again by Focus Medical Services staff to confirm it was correct. The

risk assessment included checks to exclude high blood pressure, treatment with blood thinning medicines, if patients had a pacemaker, allergies or if there was a possibility female patient could be pregnant. Guidance was available in a 'lithotripsy treatment protocols and procedures' document (2018).

If patients clinically deteriorated before, during or after the treatment, the staff at the NHS location would take the lead and act to ensure there was immediate and adequate help and support.

There were clear processes to escalate unexpected or significant findings both at the examination and upon reporting. Staff worked closely with staff in the NHS locations where they provided treatment. Following each treatment, staff handed over the care to the staff from the NHS location. The handover included details of the treatment and of any other findings or concerns they had found.

The service made sure women who attended were not pregnant before they were exposed to any radiation in accordance with Ionising Radiation (Medical Exposure) Regulations 2018. Women and children between 12 and 55 years of age were asked to sign a disclaimer to state they were not pregnant and include the last date of their menstrual cycle. A paper copy was maintained with the patient's NHS records and an electronic copy was scanned onto the services electronic records system.

Checks were completed to make sure the right patient attended for treatment. The safety checklist required two staff to check the patient's name, hospital number, date of birth and the first line of their address. This was then cross referenced with the patient's hospital wrist band each patient attending the services was issued with by the hosting NHS location.

There was no standard operating procedure to provide guidance for staff to summon help in the event a clinical emergency of patients under their care. Staff told us they would call for assistance from the nurse supporting the clinic or the consultant if they were available. We asked staff at one location we visited if there was a call bell and telephone to summon help in an emergency in the treatment room. The member of staff stated they were not sure if these were available and had to go into the room to check, and ask the nurse supporting the clinic to locate the call bell in the treatment room.

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The rationale to justify the use of x-ray during treatment sessions for individual patients, was not always documented accurately. If the use of x-ray was required during a treatment session, the radiographer had to identify in the patient's electronic record the use of x-ray was justified. This consisted of a 'yes' or 'no' response. There was a drop-down menu for staff to choose from a list of justification options, but these were not always sufficient to justify radiation exposure. For example, in one treatment the decision to use x-ray was made for a patient with a kidney stone in the ureter (the tube connecting the kidney with the bladder) and the justification was recorded as 'mobile stone'. Staff felt this was the best justification of the options available.

There was no further documented evidence in the records we reviewed where x-ray had been used, to demonstrate the thought process or rationale as to why its use was justified for the individual patient. It was unclear how the radiographer had come to the conclusion that this intervention was justified. We observed a treatment for a patient previously receiving treatment under x-ray guidance. This was not deemed as required for their third treatment despite being the same treatment delivered. We asked about the reasons for using x-ray in previous treatments, but the rationale was not documented to help justify the use of x-ray and to help inform further treatments.

Staff carried personal dosimeters to measure the radiation they were exposed to. The dosimeters were sent off for review each month and staff received new dosimeters through the post. The service monitored staff exposure to radiation and investigated if readings were higher than the legal dose limits. When readings came back higher than expected the reason was staff had been through airport security when travelling to Ireland to provide treatment.

Staff shared key information to keep patients safe when handing over their care to others. Staff handed over each patient following treatment to the NHS staff in the location where treatment was delivered. This included an overview of the treatment and how well this was tolerated by the patient. Staff instructed patients to drink between two to three litres of fluid following treatment to

help wash out the fragmented kidney stones. Further information about aftercare were given to patients by the NHS staff working to support the services delivered by Focus Medical Services.

Two technicians had undertaken an additional three-day training course in health and safety. They carried out annual health and safety risk assessments. We reviewed the last risk assessment from August 2018 which meant the annual risk assessment was overdue. The risk assessment was generic and not specific to the locations staff worked in. The health and safety risk assessment were not signed off by one of the directors and it was not clear how further actions identified to reduce risks, were shared with staff.

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.

There was no formal template used to review the staff establishment. The service had eight vans and equipment to enable them to work in eight different locations each day. Directors explained this meant they would have 12 technicians on the road each day and this showed the service regularly planned for technicians working alone. Most staff stayed in hotels when they were working to ensure they could start treatments promptly. Staff usually worked three days a week but if staff worked in Ireland, they worked five days which was then followed by a week off. Working rotas were available for staff a month in advance to enable them to plan their other home/life commitments. Staff told us this worked well and enjoyed having four days off each week.

There was no lone worker policy, risk assessment or standard operating procedure to identify safe staffing requirements when treatment was being carried out. We visited locations where there was just one member of staff carrying out treatment for a period of time. This was either the radiographer or the operating department practitioner. Despite the service being predominately low risk, there was still a risk to both staff and patients working alone. We discussed this with the directors who stated they always aimed to roster two technicians on whole day lists although half day lists were only manned by one technician.

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Working hours were monitored and the rota was planned to take into account distances travelled and anticipated finish times at hospitals. The service planned to work with either one or two lithotripsy technicians for each list depending on the length of the list, number of patients, type of load/unload and contract requirement.

The service had low staff vacancy rates. There was one vacancy for a lithotripsy technician at the time of our inspection. Staff told us the service was actively recruiting to employ another technician. The service had low turnover rates. One person had left the service in the last 12 months prior to our inspection.

The service had a proportional high level of sickness at 7% in the 12 months prior to our inspection. The service had seen a high level of sickness over the 12 months, in total this amounted to 235 days lost to sickness. The directors explained all sickness had been for valid reasons such as maternity leave, bereavement leave and long-term health conditions. Two of the directors were radiographers and they stepped in to fill rota gaps. However, this impacted on their other roles and commitments.

The service did not use any bank or agency staff as they would not be trained and competent to use the equipment safely.

Medical staffing

The service did not employ any medical staff.

Patients always remained under the care of the consultant urologist from the hosting NHS location. The service requested a clinician was always available to consult with if queries regarding their patient's treatment arose. This was included in where the service had a written contract with NHS providers, but not all treatment was delivered under a written contract. However, staff said there was access to a medical clinician in all the locations they provided services.

When children received lithotripsy treatment, this was carried out under the direct supervision of paediatric urologists and under full general anaesthetic with paediatric anaesthetists providing this. Between September 2018 and August 2019, the service had treated 15 children between the ages of one and 14 years of age and these were treated under full general anaesthesia. A further two patients aged 16 to 17 years were also treated under direct supervision of a urologist.

Records

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

Staff produced a report of patients' treatment on the day of treatment. This was printed out and placed in patients' notes. The notes covered the treatment details, the reference numbers of the equipment used, pre-treatment checks and patient details. The notes were then handed back into the care of the NHS hospital. The service did not provide patients with a copy of the report and they were not responsible for sharing the report with patients' GP.

Records were stored securely. Staff entered relevant information into patients' electronic records and scanned in paper documents to ensure all information was available to staff. Most patient records were accessed and stored securely on a third-party electronic platform. The service had permission from all hosting NHS trusts apart from one to maintain a stored electronic record of the patients record.

Staff did not have direct access to NHS hospital picture archiving and communication system (PACS) but used NHS hospital staff login details to access this information. Staff were required to check previous images as part of the justification process and to confirm the location of kidney stones before treating new patients or if patients had had additional x-rays to evaluate the effectiveness of the lithotripsy treatment.

Medicines

The service did not prescribe or administer any medicines including medicines administered as a patient group direction (PDG). PDGs provide a legal framework that allows some registered health professionals to supply and/or administer specified medicines to a pre-defined group of patients, without them having to see a prescriber (such as a doctor or nurse prescriber).

Patients received pain killers before treatment commenced and some hospitals also gave patients antibiotics prior to treatment. These medicines were prescribed and administered by NHS trust staff including the responsibilities in relation to antimicrobial stewardship.

Incidents

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There were systems to report an incident, but these were not always clear as there was no incident reporting policy. Staff recognised and reported incidents. Managers investigated incidents and shared lessons learned with the whole team.

Staff told us about the types of incident they would report knew what incidents to report and how to report them and the directors felt there was a good reporting culture among staff. There was no incident reporting policy to provide guidance for all staff including definitions of incidents and near misses they should be reporting. During our inspection, one patient developed heat blisters following treatment and this was not recorded as an incident. When we discussed this with the directors they told us they would not expect such an occurrence to be reported.

Staff we spoke with, had not had to report any incidents in the last year and there were only two incidents reported in the last 12 months. Staff were aware of the procedure to report incidents and sent a copy of the incident reporting form to the head office. However, the directors were unsure about what constituted an accident or an incident. There were separate forms to use depending on if the issue was an incident or an accident. There was a separate form to be used if there was an incident that required external reporting in line with Ionising Radiation (Medical Exposure) Regulations (2017).

There had been two accidents which had occurred in the 12 months prior to our inspection. These included a patient injuring their leg and a patient sustaining a head injury. The incidents had been investigated and included learning and actions taken following these incidents.

Staff reported no serious incidents in the 12 months prior to our inspection. Serious incidents include acts or omissions in care that result in; unexpected or avoidable death, unexpected or avoidable injury resulting in serious harm – including those where the injury required treatment to prevent death or serious harm, abuse. There had been two accidents which had occurred in the 12 months prior to our inspection. These included a patient injuring their leg and a patient sustaining a head injury. Neither accident record identified any learning or actions taken following these incidents.

The service reported one reported incident under the Ionising Radiation (Medical Exposure) Regulations, 2017 in the last 12 months prior to inspection which occurred in July 2019. This incident related to an equipment fault leading to unintentional exposure to radiation to a staff member. A thorough investigation had taken place which included immediate actions to manage the incident. The learning was then applied to all lithotripsy machines owned by the service. The incident reported identified there was a delay of six days between the incident and advice being provided by the radiation protection advisor at a local NHS trust. The incident was not reported to the Care Quality Commission (CQC), as the service deemed it did not meet the requirements in line with CQC guidance although it was considered at the time of the incident.

Staff received feedback from investigation of incidents. Feedback was cascaded to all staff by email. Some staff were able to tell us about an accident which had occurred at another location. A patient with vulnerable skin had damaged their leg when getting off the treatment bed. Learning had been cascaded to staff to advise them if a similar situation arose, to use a hospital trolley available at the hosting trust, which would reduce the risk of this occurring again due to the design of the trolley.

Are diagnostic imaging services effective?

We do not rate the effective domain for diagnostic services.

Evidence-based care and treatment

The service did not check if referrals for lithotripsy was in accordance with care and treatment based on national guidance and evidence-based practice. The service did not monitor referrals to ensure these were in line with national guidance such as National Institute for Health and Care Excellence: Renal and ureteric stones: assessment and management, 2019. This guidance set out recommendations for when lithotripsy should be offered as a treatment depending on the size and location of the renal stones. This meant we were not assured staff always correctly applied the justification process to justify exposure to radiation in line with Ionising Radiation (Medical Exposure) Regulations (2017).

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The service did not participate in national clinical audits. This was because there were not national audits they could submit data to and benchmark against.

Staff recorded and monitored diagnostic reference levels (DRLs) to ensure these met as low as reasonable required radiation dosages for the procedures they carried out. However, it was not clear how the results were used to ensure/improve patient safety. The DRL they operated to, was the length of exposure which was set at 34 seconds in 2016 and had not been altered since. Data demonstrated the average screening time was 32 seconds in a total of 10,127 treatments from August 2018 to July 2019. In the same period, 857 treatments (39%) exceeded the DRL. It was not clear how the data was used. We asked the directors to explain how this information was used to ensure patient safety. We were told the data allowed them to review data by technician and could be discussed with individuals who repeatedly used radiation in excess of the alert level of 60 seconds. It was not discussed in the minutes of the yearly meeting (21 August 2019) and there was no documented evidence this had been discussed/raised with the radiation protection advisor as these meetings were not minuted.

Staff had access to local rules for lithotripsy. Local rules summarise the key working instructions to restrict exposure in areas where radiation is used for diagnostic purposes. The local rules provided guidance for staff regarding radiation protection. They were current and were last reviewed in August 2018 and were based on current evidence-based practice and included IR(ME)R 2017. However, there was a schematic plan of the room where treatment was delivered included in the local rules did not match the locations we visited although staff could find these on request.

There was no specific policy, guidance or protocols relating to treatment of kidney stones in children. The service had a 'lithotripsy treatment protocols and procedures' (2018) in which there was a reference to the energy levels for paediatrics and the number of shocks that should be administered. This was based on the lithotripter manufacturer's guidance as there was no evidence-based practice to guide treatment.

Pain relief

Staff assessed and monitored patients during procedures to see if they were in pain. Staff did not

use a specific pain assessment tool but communicated with patients during procedures to monitor pain levels and adjusted the power level of the treatment accordingly. If patients were in a lot of pain and the treatment had to be abandoned, technicians liaised with the clinical team to discuss options such as the provision of more effective pain relief. We did not observe staff support those unable to communicate using suitable assessment tools or if additional pain relief to ease pain were required during the inspection.

Pain relief was provided by the hosting NHS location when the patient arrived for their appointment. NHS trusts managed all pre- and post-procedure care including the prescribing of medicines. Focus Medical service did not administer pain medicine to patients attending the service. Pain was routinely discussed as part of the treatment session with patients. Staff asked patients whether they were experiencing pain and explained to patients why they were felt pain. Staff also provided information about what patients could expect to experience with regards to pain as the treatment started to take effect.

The service did not review and discuss medicines used by NHS locations for patients receiving treatment and this varied greatly from one location to another. The service had produced an information booklet for hospital staff which included recommended analgesia for patients. The service recommended a non-steroidal anti-inflammatory suppository was given to patients 30 minutes before treatment in line with national guidance from the National Institute for Health and Care Excellence (NG 118, 2019). The guidance stated sufficient pain relief was essential to reach the shock wave intensity levels required to break up the kidney stones. We saw the types of analgesia varied between locations. Staff and directors told us this was the responsibility of the hosting/referring hospital to manage.

Patient outcomes

The service did not fully monitor the effectiveness of care and treatment. The service carried out annual

audits of patient treatments but only had access to a small part of the patients' journey. As a result, the service did not know the outcome of patients' treatment. Directors stated they could produce data/reports for NHS locations but were rarely asked to do so. The service did

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not request any feedback or data from NHS locations including data such as patients admitted to hospital post treatment, bleeding following treatment or 30-day post treatment mortality.

The service had an audit schedule which included four audits related to treatment. These included alert level exceeded/reason given, DRL/screening time, hospital treatment audits (how many treatments were carried out in each hospital) and stone location

In addition, the service monitored how many hours and days staff worked and how often they were required to work in Ireland.

Competent staff

Managers appraised staff's work performance and held supervision meetings to provide support and development. However, additional radiation training was not given to operating department practitioners who occasionally had to use image intensifiers to carry out procedures. There was no formal ultrasound training delivered to staff.

Managers gave all new staff a full induction tailored to their role. There was a competence framework for all new staff to complete as part of their induction. The competency framework included a training plan for different competencies to be completed each month for the six-month induction. Each member of staff had a treatment log to log the number of different treatments carried out both under and without supervision. This demonstrated they had the knowledge and skills to provide care and treatment for patients. Staff were given six months to complete these, however, they could have additional time if required at the discretion of the senior management team. New staff worked with experienced members of staff to learn the role and how to use the equipment and gain on the job experience. There was no formal training for staff in how to use ultrasound, but this was delivered to staff through onsite training.

One of the directors had oversight and signed off the member of staff as competent to work without supervision. However, the competency framework mentioned competencies to carry out 'treatment of

stones in paediatric kidney & ureter'. However, it was not stated what this entailed as there was no description of what knowledge and skills were required to treat children.

The completed competency framework was kept by the individual staff and the service did not keep any copies of this. This meant the service was unable to demonstrate all staff had completed their competency framework.

Operating department practitioners (ODPs) did not receive additional radiation protection training to ensure they had up-to-date knowledge of radiation risks and associated regulations. We discussed this with the directors who told us they tried not to have ODPs working alone. If this occurred the ODP sought advice from one of the directors, who were registered radiographers, to ensure radiation was justified. This was documented on patients' electronic treatment records by way of using the initials of the radiographer. Most treatments (82%) were carried out using ultrasound only. Following the inspection, we asked to see the working rotas for the past six months, which showed ODPs were regularly rostered to work alone in NHS locations. The directors stated this was not their normal working practice but was purely due to high level of staff absence over the last six months. This had resulted in increased treatments being delivered by one lithotripsy technician (sometimes ODPs) to avoid disruption to their service delivery."

Staff received supervision regularly. Two directors, who were radiographers, worked in a supervisory role and the rotas were planned to ensure they rotated around all staff and worked regularly with them. Rotas demonstrated that each member of staff had worked with one of the directors at least twice every year from January 2017 to August 2019.

There was an assessment framework which was intended to assess staff's ongoing competence. Directors explained these ongoing assessments offered them an opportunity to discuss techniques and address any concerns such as longer than expected radiation exposure times. However, this was not used as it was designed to and did not evidence staff's competency was regularly reviewed and assessed. We reviewed the records of three staff who had last had the assessments completed in June 2018 and 2012 and the third record showed the assessment had not been carried out since the completion of their six-month induction in 2015. When we asked the

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directors, they stated this had 'slipped' a little during a period of high levels of staff leave due to extended sickness, maternity leave and bereavement. We were not assured that competencies were regular assessed in accordance with the service's assessment framework as records did not reflect this.

Managers supported staff to develop through yearly appraisals of their work. There were no expectations from the directors for staff to complete or engage with continuous professional development over and above the training the service provided. All staff had had an annual appraisal during the 12 months prior to our inspection. The service also ensured all professional registrations were checked annually. Some staff had asked for specific ultrasound training and the directors were looking into how to provide this training to meet the needs of the individual. Directors explained they would support staff with additional qualifications of continuous development courses by allowing staff to complete the course in paid hours and would also pay for or contribute towards the course fees if required.

Directors made sure staff attended an annual team meeting or had access to full notes when they could not attend. The directors booked and arranged for a weekend away each year where staff met, completed training and had a dinner to interact socially with each other and as a team. It was a challenge to get all staff together to provide this training due to how they were geographical spread. We were told staff (including the directors) did not attend national conferences as these were expensive and offered little value to their service.

Multidisciplinary working

Staff worked alongside medical and nursing staff from the hosting NHS locations. They supported each other to provide good care. Staff at the hosting NHS locations spoke positively of the Focus Medical Services (FMS) staff. They told us there felt there were good lines of communication and that they had built up relationships with FMS staff. This was supported by two or three staff which attended particular hosting NHS locations providing better continuity, effectiveness and efficiency.

Multidisciplinary working ensured care and treatment was optimised for patients. At times the staff sought support from the consultant from the NHS hosting

locations to support with a complex case. The NHS consultants had access to additional investigations and could provide FMS with the ability to optimise treatment for the patient.

Health promotion

Staff gave patients advice following their treatment.

Staff told all patients to drink two to three litres of water following the procedure to help wash out kidney stone fragments. Staff from the hosting/referring NHS locations discussed dietary requirements with patients as required.

Consent and Mental Capacity Act

The consenting process was the responsibility of the hosting NHS locations for all patients including children. Staff confirmed consent had been sought before carrying out lithotripsy procedure. On attending the service, the Focus Medical Service staff had access to the consent form which had been signed by the patient to confirm consent and that risks and benefits of the procedure were understood and they were happy to continue with the procedure. Staff confirmed the patient had consented to treatment and recorded this in the patient's electronic record.

Are diagnostic imaging services caring?

Good 

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. We observed staff were kind and compassionate in the way they interacted with patients. Staff took time to answer questions in a kind manner ensuring patients understood the information they shared. This met national guidance from the National Institute for Health and Care Excellence (2012) QS15 Statement two: Patients experience effective interactions with staff who have demonstrated competency in relevant communication skills.

Staff were discreet and responsive when caring for patients. Staff took time to interact with patients and those close to them in a respectful and considerate way.

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We saw how staff immediately tried to make patient feel calm on attending the service for treatment. Staff engaged patients in everyday conversation topics to take their mind off the treatment they were about to receive and thereby ease their anxiety.

Patients said staff treated them well and with kindness. We saw staff were guided by the patient as to the intensity of their treatment session. One patient explained she had found the treatment difficult to tolerate due to the pain it caused. Staff provided reassurance and worked with the patient to gradually increase the intensity of the treatment at a rate the patient could tolerate and was comfortable with. Patients were reassured that treatment would stop immediately if they requested to do so.

Staff made sure patients were comfortable for the duration of their treatment. Staff recognised when patients were uncomfortable when lying on the trolley for their procedure. Additional comfort aids were provided such as additional pillows, so patients didn't have to lie flat on the trolley.

Emotional support

Staff provided emotional support to patients. Staff gave patients help, emotional support and advice when they needed it. One patient told us how they had been very anxious to attend their appointment. The patient told us the staff immediately put them at ease and had made them feel comfortable. The patient described the staff as 'lovely' and 'brilliant.'

Staff provided ongoing reassurance to patients throughout their treatment. They updated patients with regards to how long they had left and regularly checked to see if the patient was coping with the intensity of the treatment.

Staff understood the impact that a patient's care, treatment or condition had on their wellbeing and on their relatives, both emotionally and socially. Staff could empathise with patients who attended the service for treatment. They were understanding of the anxieties patients faced when attending the service and the pain they experience due to their condition. Staff did their best to provide support, advice and reassurance for these patients.

Understanding and involvement of patients and those close to them

Staff made sure patients understood their care and treatment. Staff gave patients the opportunity to ask questions about their care and treatment. We observed staff clearly explaining things to patients to make sure they understood what was happening.

Staff talked with patients in a way they could understand. On returning for treatment, a patient was asked to lie in a different position. Staff explained why this was required and the implications of not positioning themselves in this specific way.

Patients could give feedback on the service and their treatment and staff supported them to do this. Patients could use the NHS friends and family test to provide feedback although the service rarely received any feedback from NHS locations. The service carried out patient satisfaction surveys but not with any regularity. The last survey was carried out in 2018 and included responses from a total of 226 patients who had received treatment from Focus Medical Services. The response rate was low at 2%.

Feedback showed patients were treated with dignity and respect. Staff were friendly, courteous and helpful and explained treatment well. Patients reported technicians worked well with NHS doctors and nurses. Most patients (218) had confidence in the lithotripsy technician, one patient stated they were fairly confident in the technician and six patients did not comment. The survey asked patients to comment on if their special needs or requirements were met. Most patients (195) did not have special needs or requirements, 16 patients stated their needs had been met and two people stated their needs had not been met. It was not clear how the results were used as there were no documented evidence this had been discussed in the annual director's meeting held 21 August 2019. However, when we spoke with the directors they discussed the survey but did not give any examples of how the results of the survey had been shared with staff and/or used to improve services delivered.

Are diagnostic imaging services responsive?

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Good 

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.

Directors planned and organised services, so they met the changing needs of the local population. Managers worked with senior leaders in NHS organisations to plan regularly clinics up to a year in advance to meet the demand of patient care. The service was flexible to accommodate additional service delivery requests from the hosting NHS trusts. One of the locations had requested additional sessions to manage the increase in demand, and the loss of working days due to public holidays. The service had been able to accommodate this, and it was due to be formalised for the next working year which was being planned at the time of our inspection.

The NHS trusts scheduled procedure lists for the days the service was booked to facilitate treatment at a given location. The service ensured they had capacity to respond to each hospital's needs such as booking an extra procedure list to help them meet their referral to treatment national targets.

The service was mindful of the age range of patients who may require care and treatment and in a small number of locations provided Saturday clinics outside of normal working hours. This meant patients had more choice to attend and appointment which best suited their needs and life demands.

Services were planned to meet the urgent needs of the population. Most NHS locations booked patients in for a full list but accounted for one or two procedure slots on the list for any urgent patients which the hosting NHS location wanted to be treated on the same day. NHS locations paid per procedure over and above the contracted/procured procedures which was agreed.

The service was flexible to provide clinics at short notice. Staff gave us an example when a machine recently broke down and a number of patients were unable to be seen

that day. In order to make sure this issue did not impact on patients and create a backlog on the host NHS trusts waiting list, an additional clinic session was provided on the following Saturday to treat the patients who the service had been unable to see for their actual appointment.

Staff worked with the hosting hospital to make every appointment count. For example, staff undertook scans in addition to the appointment the patient was booked for to establish if kidney stones had been passed and therefore treatment was required. In another example, staff could not treat one patient as they had healthcare risks that was outside of the safe treatment recommendations. Staff performed an ultrasound scan to establish if other alternative treatments should be considered which were safer for the patient.

The service could access systems to help care for patients in need of additional support or specialist intervention if required. Patients' needs were assessed ahead of the appointment to treat and additional needs were organised by the hosting NHS location if required, such as interpreter services.

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.

The service was able to adapt treatment techniques to take into account any special needs patients may have. For example, the service had equipment to meet the needs of bariatric patients as they could bring 'heavier capacity treatment beds' if they had sufficient notice. The service had trolleys who could accommodate patients weighing up to 36 stone and found there was increasing need for this piece of equipment. The directors told us when replacing trolleys, they would purchase these trolleys to ensure they could meet the needs of patients in all locations.

Staff were aware of the importance of positioning to meet individual patient's needs. Staff provided examples of when positioning was key to managing other health conditions patients may have. For example, staff told us if a patient had a stoma bag, they would position patients in a different way to manage their additional needs. Staff told us they were very much guided by the patient as the patient was fully aware of their own condition and what

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worked and did not work for them. We observed staff to be very caring and take note of a patient's particular needs for positioning when they were unable to lie on their front.

Patient anxiety was managed effectively. A small number of anxious patients attended the service. Staff were aware anxiety was a big factor in patients not wanting to go through with the treatment. They also recognised that new patients were apprehensive as they did not know what to expect from the treatment. Staff quickly recognised anxiety and immediately tried to put patients at ease by explaining what they were going to do and by trying to take the patients mind off the treatment, by distracting them with conversation. Staff also allowed family or carers to accompany patients to help manage their anxiety to ensure treatment was optimised for the patient.

Access and flow

People were booked to attend pre-booked sessions delivered by the provider and received the right care. NHS providers booked patients in for regular lithotripsy services delivered by Focus Medical Services (FMS) and meant FMS staff did not have prior knowledge of how many patients and who they were treating. FMS only delivered the treatment whereas all other aspects and responsibility for patients remained with consultants from the referring NHS hospital. However, new national guidance from the National Institute for Care and Health Excellence (NG 118,2019) stated the first line of treatment for kidney stones should be lithotripsy and that this should be offered within 48 hours. The service was not set up to deliver responsive treatment throughout Great Britain and the Republic of Ireland within 48 hours of diagnosis but accepted these patients when they were booked to deliver treatment at NHS locations. NHS locations were responsible for managing waiting times and referral to treatment national targets.

Managers worked to keep the number of cancelled procedures to a minimum. From September 2018 to August 2019, there were a total of 655 cancelled appointments. Of these, 94% (616 appointments) were cancelled by the hospital with the remaining 39 treatments cancelled by Focus Medical Services. The most frequent reason for cancellations were equipment failure which caused the service to cancel 24 procedures.

The service monitored when patients did not attend for their scheduled procedure. Between September 2018 and August 2019, there were 444 missed appointments which accounted for 6%. The hosting NHS location was responsible for making contact with patients who did not attend and to rebook their appointment.

Learning from complaints and concerns

The service treated concerns and complaints seriously. There were processed to ensure complaints were investigated and lessons were shared with all staff. However, the service did not provide information to patients about how to make a complaint.

There were processes to manage complaints. The service had not received any complaints in the period between 25 July 2018 and 24 July 2019. However, there were processes to ensure complaints were dealt with in a timely manner in accordance with their complaints policy.

The service did not provide any information about how to make a complaint on the day or on their website. Patients, relatives and carers used the hosting hospitals complaints procedure to raise a concern or a complaint about the care and treatment they had received from the service. Managers from NHS locations would alert the directors to any complaints for them to investigate. The provider's website did not include an option to make a complaint about the service.

Are diagnostic imaging services well-led?

Requires improvement 

We rated it as **requires improvement**.

Leadership

Leaders understood and managed the priorities and issues the service faced. They were visible and approachable in the service for staff. They supported staff to develop their skills and take on more senior roles.

There was a senior leadership team consisting of three directors. Two of the directors formed the company in 1999. They were both radiographers with experience of

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carrying out lithotripsy. The third director joined the company in 2004 and became the registered manager in 2010. The directors met regularly and communicated by telephone every working day. There was one meeting held annually which was minuted. The aim of the meeting was to review the company's business and issues such as expenditure and staffing were discussed. The directors were mindful of succession planning and stated plans would be considered in the near future.

There was a clear company structure which showed different people's responsibility. All staff reported back to one of the directors. Although there were no formal meetings and recordings of discussions, it was evident staff spoke regularly with the directors and that they were responsive if issues were raised. For example, when we visited one NHS location, the radiographer had trouble logging into the electronic patient reporting system and required an update access code. This was received via text instantly.

The service was a mobile service, meaning staff carried out procedures in different hospitals throughout the UK and the Republic of Ireland. The head office was based in Exeter where one of the directors and an office administrator were based. Communication was by email to all staff and additional telephone calls if required. Two of the directors worked in a supervisory role in different locations and were easily accessible to staff.

Staff spoke positively of the directors. They told us they were always available and were supportive. Staff told us the directors cared about their wellbeing and that due to this they were able to have a good work life balance.

Vision and strategy

The service did not have a formal vision or strategy but aims and progression of the company were discussed informally and with staff during appraisals. The directors explained the roll out of new guidance from the National Institute for Health and Care Excellence (NG 118, 2019) meant the company had to review the way they were providing services. The national guidance recommended lithotripsy as first line treatment within 48 hours of diagnosis, if patients were re-admitted to hospital with ongoing pain and if the stone is unlikely to pass. In its present form, the service was unable to meet this demand and directors were reviewing possible alternative ways to be more responsive to demand.

There was a clear set of values for the service, although not all staff were able to recall these. The values included working together, quality of care, respect and dignity and efficiency. The vision was 'to be the best hospital, providing the best care, by the best people, and to ensure that patients are at the centre of all we do.' The small number of staff we asked, were not able to tell us about the service's values. They were able to tell us the vision was to provide a good service for patients and ensure they had a positive experience.

Culture

Staff felt respected, supported and valued. They were focused on the needs of patients receiving care.

Staff safety and well-being was a priority for the service. Directors took account of the personal lives of staff when planning the rota. These considerations included travel length and time, lengths of the working day for staff who may be fasting during Ramadan or flexibility with the rota to accommodate specific requests when possible. Staff told us if they felt tired after a long day and were too tired to drive, they would be able to stay in a hotel overnight to ensure they were safe. Staff told us they had a good work/life balance and this was one of the things that attracted them to work for the provider.

Staff felt their wellbeing was looked after by Focus Medical Services. Staff told us social events to support their wellbeing were a challenge to arrange due to them being geographically spread around the country. There was an annual meeting, which provided staff with the opportunity to meet with their peers and for the directors to discuss other aspects of the service provision and delivery.

Staff received bonuses through a performance and/or workload scheme. Directors explained all staff received a baseline bonus and additional bonuses at their discretion. There was an additional bonus for working as a single technician in NHS locations. Other factors of who should receive a bonus included how well directors felt individual technicians were doing and was also linked to avoidance of breakages of equipment.

Staff described the culture of the service as supportive and having a 'team mindset.' They gave us examples of how the team worked well to be supportive of each other and provide cover when someone was unwell or unable

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to cover a shift at short notice. The directors stated they were proud of how they had built up the service and that this was because NHS locations were 'happy to see the staff who attended'. They stated staff did 'a good job for the company' and that the people they worked with was their biggest asset.

Staff felt the culture of the service was 'open' and 'friendly' and they felt confident to raise any concerns with the directors. The small number of staff we spoke with, had not had the need to raise any concerns. There was no freedom to speak up guardian, but directors felt assured staff would speak up if required. The service had not carried out a staff survey.

The directors were not aware of the requirement to report on workforce equality standards data in line with the national NHS standard contract. All independent healthcare organisations with NHS contracts worth £200,000 or more annually are contractually obliged to take part in the Workforce Race Equality Standard (WRES). Providers must collect, report, monitor and publish their WRES data and act where needed to improve their workforce race equality.

Governance

Governance structures needed to be strengthened. There were no clear lines of accountability for patient safety and treatment/performance. Audits and feedback were not used to improve services and there were not regular contract reviews with NHS locations to ensure the service met expectations and/or key performance targets. However, staff were clear about their roles and accountabilities.

Governance responsibilities were shared by the three directors. However, we found there was limited scrutiny of performance and auditing of processes to provide sufficient oversight and assurance of the services provided. Data was collected but there was limited evidence of how data and audit results were used to evaluate and improve services.

There were no regular meetings with the radiation protection advisor (RPA) and medical physics who was based in a nearby NHS trust. Meetings were not minuted, so we were unsure of how often they met with the RPA.

The directors said the RPA usually responded quite quickly if they had any queries. However, recently it had been challenging to get hold of the RPA and they had not had any contact for a few weeks and were unsure why.

There was a clear patient journey mapped out. There was no formal guidance document to ensure correct referrals were received from medical staff. Directors explained referrals from senior medical staff only was accepted and stated the patient information that was required for staff to view when they provided treatment. This formed part of the patient safety checklist staff completed for each patient receiving treatment. However, it was not evident that checks were made that referrals were in line with national guidance for when lithotripsy was the preferred treatment option.

There was an inconsistent approach regarding how contracts with NHS providers were managed. There was a contract which was used with some NHS locations, but the clauses within the contract lacked clarity about responsibility and for other NHS locations it was simply a procured treatment without any contract to set out roles and responsibilities. The directors did not meet with NHS providers to review performance at any time although they told us they had discussed this as an option to adopt in the future.

Managers did not use information from the audits to improve care and treatment. We asked directors to give us examples of how audit data had been used to improve care and treatment, but they were unable to give us any examples. Audit results were not discussed in regular meetings. We found one reference in minutes of an annual meeting held in July 2018, which referred to dose optimisation (the lowest dose of radiation to achieve the best image quality). This was in response to a call from the Care Quality Commission where this was raised. There were three actions identified but it was not possible to evaluate if these actions had been completed and what the outcome was. In the meeting held 21 August 2019, there was a reference to discuss and develop staff in relation to the number of shocks and treating upper ureteric stones under ultrasound. It was stated this was because some contracts were awarded because of treatment under ultrasound guidance rather than x-ray.

When the service took on a new contract, a site visit was conducted to ensure the environment was suitable and

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to meet with the nursing staff who would be assisting the procedure lists providing pre and post procedure care. The directors gave new locations a copy of their booklet 'breaking down the facts: Information booklet: lithotripsy for hospital staff. However, there did not appear to be any discussion or review of patient pathways to ensure these met national guidance as stated in the booklet. Directors told us this would be up to the individual hospital to decide. There were no regular or annual meetings to review the contracts and discuss performance. Therefore, there were no clear lines of accountability for patient safety and treatment/performance.

There were safe recruitment processes which met the requirements as set out in Schedule 3 of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014. We reviewed five staff files which each contained the required information including two references, identity checks and employment history.

Managing risks, issues and performance

Directors identified and escalated relevant risks and issues and identified actions to reduce their impact. However, there was limited evidence about how performance was used to evaluate and improve services.

The service did not actively seek information from NHS trusts about their performance and did therefore not use this information to evaluate and improve services if this was required. This was because there were not contractual agreements to ensure feedback and performance was discussed.

There was a task risk assessment form which held information about specific risks associated with different tasks. These included slips, trips and falls, driver fatigue and manual handling, setting up equipment in treatment rooms and loading and unloading from the van. Risks were 'risk rated' in accordance with the likelihood and severity of possible harm. The form highlighted mitigating controls to reduce the risks. The risk assessment was carried out annually. This document was due for a review in August 2019. Staff were aware of the risks and mitigating actions.

There was a radiological risk assessment which assessed the risk to employees, outside workers and members of the public when radiation was used. The risk assessment

set out mitigating actions which included used of personal protective equipment (lead aprons and thyroid collars). The risk assessment was based on Ionising Radiation (Medical Exposure) Regulations, 2017 and was last assessed in January 2019.

There was a provider risk register which had six risks recorded. These included: loss of work, machinery, staff retention, theft, adverse weather and Brexit. The risks were categorised, and the level of risks was assessed based on the probability of the risk occurring. Three of the risks were rated as high risks: loss of work, theft and Brexit. Mitigating actions were documented and who was responsible for implementing these, but it was not assessed how these would reduce the risks. The risk register was last reviewed in January 2019. It was not specifically discussed and reviewed in the annual meeting held in August 2019, although the minutes of the meeting showed some of the risks had been discussed. The risks on the risk register reflected the concerns the directors discussed when asked.

Managing information

The service collected reliable data but did not analyse this to identify where service improvements could be made. The service carried out audits but did not use this information to review and evaluate the service the provided. There were no action plans to demonstrate how service improvements were identified, implemented and completed.

Electronic patient records were password protected. Staff could find the data they needed, and information systems were integrated and secure. Data or notifications were mostly submitted to external organisations as required.

Staff did not always have access to up-to-date, accurate and comprehensive information on patients' care and treatment. Information needed to deliver safe care was not always available to staff in a timely and accessible way. Staff used the login details of a member of staff from the hosting NHS location to access the electronic picture archiving and communication system (PACS). We saw the login details of the host NHS staff written down on a paper towel, visible to all who accessed the room. It was unclear why the service did not have their own login details for a system which was used for the large majority of patients visiting the service.

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The service used an electronic system to store important documents and information which all staff had access to. One month prior to our inspection the service had moved to using an electronic platform which was accessible using a computer or a mobile telephone. The platform provided staff access to information such as, policies, the local rules, and the working rota. At the time of our inspection documents were still being uploaded to the platform. Staff told us they had started to get used to the system and it was helpful to also have access via their mobile telephones.

Engagement

Leaders and staff engaged with patients. The service monitored patient feedback. We reviewed a patient satisfaction survey carried out from August 2018 to February 2019. The survey consisted of eleven questions ask and a total of 226 people completed the survey. The questions asked related to for example dignity and respect, questions being answered and about confidence in the technician's ability. The results were largely positive.

The service did not carry out any staff surveys. Directors explained the annual appraisals offered all staff an opportunity to discuss any issues of concern they may have.

Outstanding practice and areas for improvement

Areas for improvement

Action the provider **MUST** take to improve

- The provider must ensure staff receive adult safeguarding and child protection training to meet national guidance and ensure the safeguarding lead completes safeguarding training at the appropriate level in accordance with national guidance. The provider must develop a child protection policy.
- The provider must strengthen governance and risk management processes to ensure performance and audit data receive sufficient scrutiny to identify service improvement opportunities.
- The provider must develop policies for incident reporting (including reference to duty of candour responsibilities), a training policy, a chaperone policy, lone worker policy and a paediatric policy, which should include reference to Gillick competencies, to provide guidance for staff.
- The provider must ensure there are regular meetings with the radiation protection advisor and that these meetings are minuted to ensure agreed actions are completed.
- The provider must consider ways to promote engagement and contracts with NHS providers to ensure sufficient oversight. Including agreed roles and responsibility are clearly defined to ensure patient safety.
- The provider must ensure copies of competency assessments are kept in staff files to demonstrate staff competency training.
- The provider must review training for operating department practitioners who carry out treatment using the image intensifier and for all staff using ultrasound to ensure staff have the required training and competencies to safely undertake treatment.

Action the provider **SHOULD** take to improve

- The provider should enhance processes for the prevention and control of infection.

- The provider should review policies/standard operation procedures to add references to demonstrate policies are based on current and evidence-based practice.
- The service should improve compliance with annual servicing of equipment to maintain ageing equipment and ensure these are remain safe to use, including lead aprons and thyroid collars.
- The provider should review processes to gain oversight through auditing of daily cleaning, quality assessment and calibration of equipment to demonstrate compliance.
- The provider should investigate high kV levels of image intensifiers to ensure these remain safe to use.
- The provider should review the audit schedule to include auditing of documentation, safety checklist and justification of exposure to radiation.
- The provider should review processes to sign off annual health and safety risk assessments.
- The provider should improve awareness of emergency procedures in NHS locations in case of a clinical or other emergency.
- The provider should review processes for referral of patients to ensure these are suitable for lithotripsy treatment in line with national guidance.
- The provider should report on work race equality standards in line with the standard NHS contract.
- The provider should explore how to inform patients about how to make a complaint about the service.
- The provider should develop the role of a freedom to speak up guardian and develop a policy to support this role.
- The provider should work with NHS trusts to enable FMS staff to obtain access to picture archiving and communication systems.
- The provider should ensure all relevant external stakeholders are informed of IR(ME)R reportable incidents.

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

Diagnostic and screening procedures
Treatment of disease, disorder or injury

Regulation

Regulation 12 HSCA (RA) Regulations 2014 Safe care and treatment

Regulated activity

Diagnostic and screening procedures
Treatment of disease, disorder or injury

Regulation

Regulation 13 HSCA (RA) Regulations 2014 Safeguarding service users from abuse and improper treatment

Regulated activity

Diagnostic and screening procedures
Treatment of disease, disorder or injury

Regulation

Regulation 17 HSCA (RA) Regulations 2014 Good governance

Regulated activity

Diagnostic and screening procedures
Treatment of disease, disorder or injury

Regulation

Regulation 18 HSCA (RA) Regulations 2014 Staffing