

Harmonic Medical Sonography

Quality Report

Parkway One (Ground Floor)
Parkway Business Centre
Princess Road
Manchester
M14 7LU

Tel: 0161 226 9259

Website: www.harmonicmedicalsonography.com

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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

Good



Are services safe?

Good



Are services effective?

Good



Are services caring?

Good



Are services responsive?

Good



Are services well-led?

Good



Overall summary

Harmonic Medical Sonography is operated by Harmonic Medical Sonography Limited. The location has been registered to deliver diagnostic and screening procedure services since April 2015.

The location, which is also the provider's head office, is the administrative and managerial centre from which the provider's diagnostic imaging services are managed. In addition, the provider operates from several community locations across the country, providing a service through

Summary of findings

both primary healthcare and NHS institutions. At the time of the inspection the Manchester location did not host any regular clinics on site; however, there are facilities to see patients privately, including children.

The services move between local clinics on a rota system, providing a convenient and community-based option for patients who have been referred by their GP. In addition, the service runs several flexible clinics where the focus is accommodating patients who cannot make it in the normal hours of the week; for example, evenings, weekends and bank holidays. For patients referred by their GPs, these services offer fast access to a range of ultrasound scanning.

The provider delivers a range of diagnostic scanning and screening services. The most common procedures were ultrasound scans in the following areas; general medical, gynaecological, musculoskeletal, vascular (deep venous thrombosis), small parts for example neck, glands and lump scans.

We inspected this service using our comprehensive inspection methodology. We carried out a short-announced inspection on the 27 February 2019.

To get to the heart of patients' experiences of care and treatment, we ask the same five questions of all services: are they safe, effective, caring, responsive to people's 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 have not previously rated this service. We rated it as **Good** overall, because:

Following this inspection, we told the provider that it should make some improvements, even though a regulation had not been breached, to help the service improve. Details are at the end of the report.

- Safe care and treatment was provided by staff that had received mandatory and safeguarding training appropriate to their roles. Staff were aware of how to raise safeguarding concerns, and appropriately assessed, responded to and recorded any relevant patient risks.

- Staff followed infection control protocols and equipment was appropriately cleaned.
- There were sufficient staff, who worked flexibly, to meet the needs of the service. Staff knew how to recognise and report incidents.
- Staff provided effective care in line with evidence-based practice, national and professional guidelines.
- Staff were appropriately qualified and had the skills and knowledge to undertake their roles effectively. They understood the need for consent and to make adjustments for patients who may require additional support. The provider monitored its outcomes and used these to improve its services.
- Care was delivered by staff who were compassionate and helped to maintain people's privacy and dignity. Staff supported their patients and took time to explain the procedures being carried out and gave people time to ask questions.
- The provider continually assessed demand at its clinics, and planned its services to meet the needs of the local population. Staff took account of individual patient's needs, including those who needed additional support.
- Clinics were planned flexibly to meet patient need, and patients were given a choice of appointments.
- Complaints were taken seriously, reviewed in the clinical governance meetings and learning was shared with staff.
- The provider had the appropriate skills and knowledge to lead the service, and they had a vision and plans in place for future development of the service.
- The provider could describe the potential risks to the service, and these were appropriately reviewed through the clinical governance committee.
- The service was committed to improving its services and developing.
- The service engaged with patients and with referrers and supported a culture of continual learning and improvement.

Ellen Armistead

Summary of findings

Deputy Chief Inspector of Hospitals (North)

Summary of findings

Our judgements about each of the main services

Service

Diagnostic imaging

Rating

Good



Summary of each main service

This was a limited company providing a diagnostic imaging service.

We rated this service as good because it was safe, caring and responsive. The governance and risk management arrangements were good.

We do not rate effective for this type of service.

Summary of findings

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Good



Harmonic Medical Sonography

Services we looked at

Diagnostic imaging

Summary of this inspection

Background to Harmonic Medical Sonography

Harmonic Medical Sonography is operated by Harmonic Medical Sonography Limited. The service opened in April 2015. The head office is in Manchester. The provider is registered to deliver diagnostic and screening procedure services.

The location is the administrative and managerial centre from which the provider's diagnostic imaging services are managed. At the time of the inspection the location did not host any clinics on site; however, it did provide a diagnostic imaging service for adults or children as private patients.

The provider manages its range of ultrasound scanning services and is regulated by CQC from the location.

The registered provider is also the registered manager.

The service performs ultrasound scans of a wide range of body areas including general medical ultrasound, involving the abdomen, gynaecological and obstetric ultrasound, musculoskeletal system, soft tissue masses, vascular ultrasound particularly deep venous thrombosis and small parts; for example, neck, glands and lump scans.

At the time of the inspection the provider delivered community based mobile ultrasound services across a number of clinical commissioning groups on behalf of the NHS. The services move between local clinics providing a community based option for patients who have been referred by their GPs. At the time of this inspection ultrasound scanning was held at four satellite clinics in Staffordshire and nine satellite clinics in East Sussex.

Our inspection team

The team that inspected the service comprised of a CQC lead inspector, and a second CQC inspector. The inspection team was overseen by Judith Connor, Head of Hospital Inspection.

Why we carried out this inspection

Start here...

How we carried out this inspection

Start here...

Information about Harmonic Medical Sonography

The location manages the provision of diagnostic imaging services. It is registered to provide the following regulated activities:

- Diagnostic and screening procedures.

During our visit, we inspected the facilities. We spoke with the manager/clinical director who was the lead sonographer, another sonographer and two patient

administrators. We observed the treatment of a patient who was having a scan during the inspection. In addition, we telephoned four patients to ask them about their experiences of care. We reviewed five sets of patient records.

In addition to the managing/clinical director, the service employed two full time sonographers, and regularly used

Summary of this inspection

the services from two additional sonographers on a self-employed basis. The director had access to a consultant advisor on a consultancy basis and had input from a business development manager and a business operations manager.

There were no special reviews or investigations of the service ongoing by the CQC at any time during the 12 months before this inspection. The service has not been previously inspected.

Activity

- In the financial year January 2018 to December 2018, the provider carried out 9,019 ultrasound scans. The ultrasound scans ranged from general abdominal scans of which 2,456 were carried out in the above time frame, 2,238 gynaecological scans (both transabdominal and transvaginal scanning), 1,584 musculoskeletal scans, 1,434 urinary tract scans and 524 soft tissue scans.

Track record on safety

- No never events, serious injuries or deaths
- No clinical incidents
- The service had no incidences of any healthcare acquired infection since opening in April 2015

Services accredited by a national body:

- The service had no accreditations at the time of this inspection

Services provided under service level agreement:

- Clinical and or non-clinical waste removal
- Interpreting services
- Grounds maintenance
- Maintenance of medical equipment

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 **Good** because:

- The service provided mandatory training in key skills to all staff. Staff attended an induction and told us they were supported to attend training.
- Staff understood how to protect patients from abuse and the service worked well with other agencies to do so. Staff had training on how to recognise and report abuse and they knew how to apply it.
- The provider had appropriate processes and procedures to manage the control of infection risk in satellite clinics.
- The location had suitable premises and equipment.
- Staff requested and recorded relevant information to assess and respond appropriately to individual patient risk. Staff maintained records which were clear and up-to-date.
- The service had enough staff with the right qualifications, skills, training and experience to keep people safe from avoidable harm and to provide the right care and treatment.
- The service managed patient safety incidents well. Staff recognised incidents and reported them appropriately.

However,

- At the time of the inspection the training information was held in individual staff files and had not been collated into a format that would readily give oversight of completion figures, however since the inspection the manager has been positive in their response to our concern and has submitted a detailed mandatory training and induction policy, including a training needs analysis.

Good



Are services effective?

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

- The service provided care and treatment based on national guidance and evidence of its effectiveness. The manager checked to make sure staff followed guidance.
- The managers monitored the effectiveness of care and treatment and used the findings to improve them.
- Staff had the right qualifications, skills, knowledge and experience to do their jobs.

Good



Summary of this inspection

- Staff worked together as a team to benefit patients. Sonographers and administrative/chaperone staff supported each other to provide good care.
- Staff understood how and when to assess if a patient had the capacity to make decisions about their care. They were aware of how to follow the policy and procedures if a patient was unable to give consent.

Are services caring?

We rated it as **Good** because:

- Staff cared for patients with compassion. Feedback from patients confirmed that staff treated them well and with kindness.
- Staff provided emotional support to patients to minimise their distress. For example, if they were anxious about having a transvaginal scan.
- Staff involved patients and those close to them in decisions about their care and treatment.
- Patients said staff explained the procedure and a sonographer told us they did this to provide patients with reassurance to minimise anxiety.

Good



Are services responsive?

We rated it as **Good** because:

- The service planned and provided services in a way that met the needs of the people who attended the service.
- The service took account of patients' individual needs.
- People could access the service when they needed it.
- The service treated concerns and complaints seriously, investigated them and learned lessons from the results, and shared these with all staff.

However,

- The services leaflet did not accurately reflect the services it provides.
- The services complaints process wasn't in line with current guidance.

Good



Are services well-led?

We rated it as **Good** because:

- The managers had the right skills and ability to run a service providing high-quality sustainable care.

Good



Summary of this inspection

- The provider had a vision for what they wanted the service to achieve and had workable plans to turn it into action that encompassed staff, patients, referrers and clinical commissioning groups representing the local communities.
- The managers promoted a positive culture that supported and valued staff, created a sense of common purpose based on shared values.
- The provider used a systematic approach to continually improve the quality of its service by creating an environment in which excellence in care would flourish.
- The provider had systems to identify risks, plan to eliminate or reduce them, and cope with both the expected and unexpected.
- The provider collected, managed and used information well to support its activities.

However,

- The services policies included information that was not relevant to the service provided.
- At the time of the inspection the recruitment of a consultant radiologist /sonography practitioner to sit on their clinical governance committee to provide independent oversight was not yet in post.






Detailed findings from this inspection

Overview of ratings

Our ratings for this location are:

	Safe	Effective	Caring	Responsive	Well-led	Overall
Diagnostic imaging	Good	Good	Good	Good	Good	Good
Overall	Good	Good	Good	Good	Good	Good

Diagnostic imaging

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

Are diagnostic imaging services safe?

Good 

Safe means the services protect you from abuse and avoidable harm. We have not previously rated this service. We rated it as **good**.

Mandatory training

- The service provided mandatory training in key skills to staff and we were assured that the service had oversight that everyone had completed it.
- The staff files included certificates of completed staff training. Mandatory training was delivered by an external training provider face-to-face or by staff having completed this in their employing NHS Trust.
- The manager was confident the staff had appropriate training, however at the time of the inspection the training information was held in individual staff files and had not been collated into a format that would readily give oversight of completion figures. We raised this with the manager at the time of the inspection and the service has been positive in its response to our concern and submitted a detailed mandatory training and induction policy including a list to show a training skills analysis and when staff were due to complete a training refresher course.
- Two administrative members of staff had completed face-to-face training in December 2018 from an external health and safety provider. This practical training was aligned to the skills for Health UK Core skills training framework. Training included first aid, fire safety, basic life support, adult and children's safeguarding. In

addition, this training included information technology training for sending images, data protection, information governance and handling information securely.

- Additional training was provided for clinical staff; for example, advanced life support, infection control, including a practical session and lone working.
- The service had provided clinical placement training for the last two years for Salford, Bournemouth and West England university students for those undertaking sonography courses. The students followed competencies set by the university.
- Staff spoke positively about the content and the quality of training they had received from the training provider.
- All staff completed an induction programme.

Safeguarding

- The service had systems and processes in place to ensure people were kept safe. Staff understood how to protect people from abuse. Staff had training on how to recognise and report abuse and worked with other agencies to apply it.
- The registered manager had completed adult and children's safeguarding to level two and following the inspection has carried out level three training in April 2019.
- All staff had completed safeguarding vulnerable children and safeguarding vulnerable adults level one and two training. This was in line with intercollegiate safeguarding guidelines. In addition, one sonographer had completed level three children's safeguarding training.

Diagnostic imaging

- The safeguarding adult and children's lead was the registered manager/clinical director. They had taken on this role due to a period of absence of the former safeguarding lead who was the operations director and a qualified social worker.
- The service operated from various health centres or clinics across the country so staff were required to be aware of the local safeguarding policy from different areas. The four staff we spoke with had the contact numbers for the various health centres and clinics, which we were told were on display in the out of area clinics. In addition, the sonographers had a laminated copy of contact numbers which they took with them for ease of access. The ultrasound staff reported they always had access to staff within the satellite clinics and were aware of who was the safeguarding lead within these services. Staff told us there was an out-of-hours contact number for emergencies and staff knew where to go to obtain further advice if needed.
- The provider had a safeguarding vulnerable adults' policy and a safeguarding vulnerable children policy, which had been updated in September 2018. These included links to relevant guidance documents.
- Staff were aware of their roles and responsibilities and how to raise matters of concern. A staff member told us they would report a safeguarding incident to the manager and the four staff we spoke with could clearly describe what a safeguarding incident was.
- Staff had received training in female genital mutilation and the PREVENT strategy for identifying and preventing radicalisation. Two of the sonographers we spoke with were aware they had a legal duty to report cases of female genital mutilation. The services safeguarding policy referred to up to date guidance, including latest guidance from the Royal Colleges Intercollegiate Document, Safeguarding Children and Young People September 2010.
- We saw evidence that staff had enhanced disclosure and barring service checks; however, the policy did not include a timeframe for when they planned to renew these. We discussed this with the clinical lead who advised us they would address and amend this.
- All staff had completed safeguarding vulnerable children and safeguarding vulnerable adults level one and two training. This was in line with intercollegiate safeguarding guidelines. In addition, one sonographer had level three children's safeguarding training.
- Children would be scanned at the Manchester location under private patient arrangements. The three children who had been scanned in the last 12 months were accompanied by a parent or guardian. Staff were aware of the process to follow to obtain advice from the safeguarding lead, or to raise a safeguarding alert or concern via the reporting system.

Cleanliness, infection control and hygiene

- The service controlled infection risk well. Staff kept themselves, equipment and the premises clean. They used control measures to prevent the spread of infection.
- The location did not host any clinics currently but was used for scans of private patient as required. The provider had policies and procedures to manage the control of infection risk in satellite clinics.
- The clinic and the two ultrasound rooms were visibly clean and tidy. Staff followed good practice guidance in relation to the control and prevention of infection.
- The registered manager was the infection prevention and control lead for the service.
- The provider had an infection control policy, which was last approved and reviewed in September 2018. In addition, the provider had an ultrasound probe decontamination policy for the cleaning of invasive equipment, which was last reviewed in November 2018. The infection control policy referred to safe sharps management, which was not wholly relevant for this service. We discussed this with the manager who told us they would review this. The policy was supported by a waste management protocol on the management of clinical, non-clinical, and household waste.
- The provider reported no incidences of healthcare acquired infections across its services in the twelve months prior to the inspection.

Diagnostic imaging

- Sonography and chaperone/ assistant staff we spoke with were aware of the 'arms bare below the elbow' protocol, which we were told was followed when providing care to patients at the satellite clinics.
- Staff told us how they cleaned probe equipment after each use in line with their policy. Single-use rubber sheaths were used with transvaginal probes to reduce the risk of infection; probes were thoroughly cleaned after each use.
- The provider used a hand hygiene policy. This included how staff should clean their hands. The ultrasound room had a sink to wash hands. Hand washing instructions were available in the consulting rooms. In addition, alcohol hand gel was available at the entrance to the clinic. Staff told us they had access to personal preventative equipment such as gloves and aprons to prevent the spread of infection. We observed the sonographer appropriately wash their hands before and after carrying out a transvaginal scan.
- Infection prevention and control audits for hand hygiene and cleanliness were carried out using the World Health Organisation patient safety observations. For the period January to December 2018, the hand hygiene audit, which involved 1400 patients, revealed 99.4% compliance. The results were fed back to staff and actions for any required improvements were made and monitored during the governance meetings.
- A cleaning protocol was followed before the consulting rooms were used between patients.
- The provider confirmed the landlord carried out periodic testing of water and the ventilation environment for quality and Legionella's disease. We saw the contract and the checklist for the water testing.
- The provider reported they undertook audit exercises in several areas including clinic rooms, computer workstations, areas around hand-wash basins, scanning equipment itself including ultrasound probes to reduce cross infection to a minimum. We requested copies of these audits at the time of the inspection but had not received them to comment on in this report.
- The clinical manager received weekly feedback on the service the cleaning contractors provided. We saw the cleaning checklist for the general housekeeping. Although the environment appeared clean and orderly, the checklist had not been signed since November 2018. We raised this during the inspection with the clinical manager who told us this would be addressed.
- The business development manager worked with the satellite clinics and health centres management teams when agreeing contracts to ensure that the premises being used for clinics were appropriate for the service. This included ensuring that privacy curtains, wash basins, cleaning and other appropriate infection control measures were in place.

Environment and equipment

- The head office had suitable premises and equipment and looked after them well.
- The premises were modern in a business park with parking. The office included a large reception area, two offices, two treatment rooms on the ground floor of a shared use office complex. The building and the offices were accessible for people using wheelchairs and a lift was available for any visitors or staff to access toilet facilities on the first floor. Staff kitchen facilities were available within the office space. There was an onsite restaurant, accessible to staff and the public.
- A range of administrative and managerial functions were carried out at the head office, with the booking office occupying one of the rooms. Electrical equipment within the offices had been safety tested.
- Ultrasound scanning equipment was tested and maintained through maintenance contracts with third party suppliers. We viewed the portable appliance testing logs held by the provider which confirmed that all machines more than 12 months old had been safety tested.
- Access from the main waiting area to the diagnostic imaging areas on the ground floor was via a secured door, to prevent unauthorised access. The scanning/ consulting rooms were lockable to maintain patients' dignity and privacy.

Diagnostic imaging

- The ultrasound machines were password protected and patient data and scan information was securely stored. Following scans, the images were subsequently transferred by email to the provider who manually uploaded these to the picture archiving and communication system. The scans were reported on by the sonographers.
- The ultrasound machines were visibly clean. We saw completed inspection and cleaning charts, and operating manuals were readily available. An external cleaning company cleaned the floors, surfaces and environment. The clinical manager received weekly feedback on the service they provided. Cleaning products were adequately stored under the Control of Substances Hazardous to Health Regulations 2002.

Assessing and responding to patient risk

- Risks to people were assessed, and their safety monitored and managed so they were supported to stay safe.
- Staff requested and recorded relevant information to assess and respond appropriately to individual patient risk. They kept clear records and asked for support when necessary.
- The care pathway protocols policy provided a framework for the receipt and processing of diagnostic ultrasound referral requests, including the processes for scanning and reporting of ultrasound diagnostic reports.
- The protocols provided an urgent scanning and reporting pathway, which also facilitated the urgent report of unexpected findings.
- Urgent scan requests were processed within 24 hours. Sonographers immediately reported the outcome of urgent requests, or unexpected abnormal findings, direct to the referrer by telephone after the patient examination was complete.
- There were occasions when sonographers or consultants required a second opinion on cases or images. The service would accommodate these requests and respond formally within a two working day turn around. In the case of being unsure of findings, the sonographer would record enough images to demonstrate the pathology to the best of

their ability. We were told by the manager the case would then be discussed with the senior sonography practitioner. The sonographer we spoke with confirmed this did occur.

- The written report for any urgent scans were prioritised by the sonographer for same day transmission to the referrer by secure email or by secure fax.
- The two sonographers we spoke with were aware of the protocol and could describe the actions they would take with urgent scans and for unexpected abnormal findings.
- The provider's referral, vetting and booking guide prompted staff to request and record details from patients of any disability or mobility issues they may have. The administration staff also provided scan-relevant preparation advice to patients when confirming the appointment.
- All staff had undertaken basic life support training and those we asked were aware of, and were able to describe, the actions they would take to contact the emergency services immediately in the event of a patient collapse.

Staffing

- The service had enough staff with the right qualifications, skills, training and experience to keep people safe from avoidable harm and to provide the right care and treatment.
- The sonographers described how they had support networks from staff at the clinics they worked from to meet the needs of patients and to maintain staff safety as required, for example if they were required to make a safeguarding referral or a patient became unwell. The students on placement from ultrasound imaging courses may accompany the sonographer as a chaperone as required.
- Staffing was planned by the manager for each clinic to cover the patient appointment slots, and to fulfil the requirements of its commissioners. The provider continually assessed and monitored staffing levels and reported there were enough staff to carry out clinics as required.

Diagnostic imaging

- Due to the nature of the provider's services, the sonographers were based in or travelled to provide the service in clinics and health centres in several satellite locations across the country.
- At the time of the inspection, the manager was the full-time lead sonography practitioner and employed two full-time sonographers. In addition, two bank sonographers worked on an as and when needed basis. The staff were supported by two full-time sonography assistants/administrators.
- The manager/clinical leader provided leadership, managerial and IT support. A business development director provided part time managerial assistance with contractual processes within the organisation.
- At the time of the inspection, the provider was recruiting for a consultant clinical advisor. In the meantime, the manager told us a practising radiologist provided advice as required.
- Between August and November 2018, the provider reported that one shift had been covered by a bank sonography practitioner.
- Routine written reports were sent to the referrer approximately two to five days after the scan. At the time of the inspection, the sonographers were reviewing and sending reports of the previous working day's scans.
- Urgent written reports were sent within 24 hours of the scan, and could be sent same day if requested. Reporting and sonography staff confirmed that referrers were immediately informed of any abnormal findings by telephone.
- If the referrers had access to the same shared picture archiving and communication system, reports were available via that system. Otherwise reports were sent by secure email.

Medicines

- The provider did not hold any medicines or controlled drugs.

Incidents

Records

- Staff kept detailed records of patients' care and treatment.
- The provider had a records management / health records policy, which was last updated in February 2018. The policy set out staff responsibilities for managing records appropriately, and linked to relevant legislation and guidance.
- We reviewed five patient scan reports. The reports we viewed were clear and included relevant information and differential diagnosis findings in line with the Standards for Reporting and Interpretation of Imaging Investigations 2006 guidelines of the Board of the Faculty of Clinical Radiology.
- Scans were stored securely to maintain patient data and privacy in line with the General Data Protection Regulation 2016, the regulation on data protection and privacy for all individuals. Scans were stored on a hard drive and then within a recognised picture archiving and communication system. This is a networked software system for managing medical images and reports.
- All reports were checked by the senior sonographer before being sent to the referrer.
- The service managed patient safety incidents well. Staff recognised incidents and reported them appropriately. Staff had reported two incidents since May 2018. We saw evidence that incidents were discussed, and learning was shared in the clinical governance meetings and staff meetings.
- The provider had a serious incident policy. Incidents were reported and managed at provider-wide level in line with the policy. Staff would complete a Harmonic Medical Sonography incident form and email this to the clinical director.
- We saw evidence that incidents were discussed, and learning was shared in the clinical governance meetings and staff meetings.
- The provider reported no never events in the twelve months prior to the inspection. A never event is a serious incident that is wholly preventable as guidance, or safety recommendations providing strong systemic protective barriers, are available at a national level, and should have been implemented by all providers. The event has the potential to cause serious patient harm or death, has occurred in the past and is easily recognisable and clearly defined.
- The provider had a duty of candour policy. Duty of candour is a regulatory duty that relates to openness

Diagnostic imaging

and transparency and requires providers of health and social care services to notify patients (or other relevant persons) of certain notifiable safety incidents and provide reasonable support to that person. The two sonographers we spoke with were aware of the duty of candour.

- The policy set out staff responsibilities at all levels of the organisation to be open, honest and to communicate timely with patients in all incidents where the patient had been exposed to moderate or severe harm, or death.
- Staff we asked could describe the types of incidents they would report, and how they would do this. Staff were aware of how to obtain further advice on a potential incident if they were unsure.

Are diagnostic imaging services effective?

Good 

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

Evidence-based care and treatment

- The service provided care and treatment based on national guidance and staff had access to best practice guidelines via the intranet.
- The manager checked to make sure staff followed best practice guidelines.
- The provider's policies and procedures considered guidelines from a range of national and professional bodies. These included, although were not limited to, The British Medical Ultrasound Society Safety Statements (2007 to 2017) and The Royal College of Radiologists' Standards for interpretation and reporting of imaging investigations (March 2018).
- The provider's clinical manager was responsible for reviewing and updating the provider's policies, pathways and guidelines in line with updated national guidance. Changes to policies were agreed and ratified through the provider's clinical governance committee.

- Policy and procedure updates were shared with staff by email and in staff meetings. A confirmation process was in place to ensure that staff read updates.
- Staff could access the scanning guidelines protocols, policies and procedures when working remotely as these were stored centrally on the provider's computer system.
- We reviewed a range of policies and procedures during and after the inspection. These were in date, with version history recorded, and had been appropriately reviewed and approved.

Nutrition and hydration

- Water dispensers were available for patients awaiting scans if additional hydration was required.

Pain relief

- The service provided diagnostic scans of patients who might be experiencing pain.
- The location did not hold any medicines, including pain relief medicines. Due to the nature of the scans carried out at satellite clinics, the provision of pain relief medicine was not required.
- However, staff were aware of the need to sensitively review patients' mobility levels and comfort when positioning them on the treatment table for scans. Staff members confirmed they would ask patients if they were in any pain or discomfort.

Patient outcomes

- The manager monitored the effectiveness of care and treatment and used the findings to improve them.
- The service was subject to a range of key performance indicators agreed between the provider and the local clinical commissioning groups for the satellite clinics.
- Between January 2018 and January 2019, the provider reported performance against a number of key performance indicators, which were recorded monthly. We reviewed evidence from four of the providers reports to commissioners that no patients waited over six weeks from referral to treatment for a diagnostic test.
- The provider also monitored the following: forwarding a written clinical report to the referring clinician within two days (or the service user's GP when this was not

Diagnostic imaging

the referral source); contacting the patient within five days; and, scheduling appointments within ten days of the date the referral was received. The data showed that the provider met, or exceeded, its targets for all these measures.

- The provider reviewed and evaluated the quality of three key components of the clinical pathway for imaging examinations; the referral, imaging, and reporting. At the time of the inspection the clinical manager checked all the scan reports before they were sent out. Between January 2018 and January 2019, 99% of cases reviewed showed the quality of images produced by the sonography practitioners to be excellent. In addition, the reports were found to be accurate, clear and precise.
- We saw the audit reports of four sonographers including where the clinical manager had made a recommendation for improving the classification of reported findings on one report. It was recorded that feedback and learning had been given verbally to one of the sonographers.
- In response to some of the people attending for scans without full bladders for urology ultrasound scans, the clinical manager had started an audit on bladder filling. This was work in progress at the time of the inspection.
- The clinical manager told us of plans in place to develop an internal peer review system for the sonographers to enable them to 'quality assure' each other's clinical practice. This would involve observing colleagues when undertaking a range of ultrasound examinations and to provide professional feedback to drive the agenda for quality improvement within their ultrasound services.
- From the reports we viewed, the images were of a high quality. The service aimed to provide the best quality images they could.

Competent staff

- The service made sure staff were competent for their roles. The manager appraised staff's work performance and held supervision meetings with them to provide support and monitor the effectiveness of the service.

- Staff had the skills, knowledge, and experience to deliver effective care and treatment.
- The provider had an induction and probationary programme which all staff, including any bank and agency staff, were required to undertake prior to starting their duties. We saw evidence of completed staff induction programmes.
- Staff were trained in core subjects such as infection control, safeguarding and health and safety.
- The provider had a staff performance and appraisal policy. Staff appraisals were carried out every 12 months. When staff joined the company an appraisal review was held prior to the probationary period ending. Records showed a 100% appraisal completion rate.
- Continuous professional development was on going. All employees were encouraged to engage and participate in the company's personal development programmes. One sonographer was undertaking a course in musculoskeletal ultrasound and told us they had a leadership and mentorship role coordinating the training of the university students whilst on placements.
- Sonography practitioners were encouraged and had attended professional courses including the annual British Medical Ultrasound scientific conference and others that may be recommended by the Society and College of Radiographers. The sonographer told us they felt well supported by the clinical manager.

Multidisciplinary working

- Staff of different kinds worked together as a team to benefit patients. Doctors, nurses and other healthcare professionals supported each other to provide good care.
- Sonographers, healthcare assistants, students and administrative staff worked together to provide the service to patients. Staff at the service worked closely with the referrers to enable patients to have a prompt diagnosis and promote a seamless treatment pathway. If they identified concerns from scans they escalated them to the referrer.
- Staff described a good working atmosphere, and spoke positively about working with their colleagues and the clinical manager.

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- We observed effective communication and working practices between sonography and the administrative and managerial staff. The administration staff felt part of the team and were involved in developing and improving the administrative services.

Seven-day services

- The service provided a flexible service by offering flexible scan times.
- The clinics were run flexibly where the focus was to accommodate patients who were unable to make it Monday to Friday 9am to 5pm. Scans were provided during evenings until 8pm and weekends as required.
- For patients referred by their GP's, patients were offered fast access to a range of ultrasound scans.

Health promotion

- The service did not provide a role in health promotion; however, health information leaflets were available at the reception desk. Examples of leaflets included; rheumatoid and osteoarthritis and its management, breast awareness and cancer related leaflets.

Consent and Mental Capacity Act

- The provider had a consent policy in place. Staff were confident in seeking consent from patients and when spoken with understood how mental capacity should be assessed. The employee handbook included information around consent, including Gillick competency advice that included the duties and responsibilities of all staff members. (Gillick competency is a test of whether a child of 16 years or under is capable of making decisions about their care and treatment).
- The manager told us the three children who had attended for scans in the previous 12 months had been accompanied by a parent/guardian.
- Three staff told us they had received consent training at induction.
- Verbal or implied consent was obtained before procedures were carried out. Written consent from the patient was obtained for any invasive scans such as transvaginal scans.

- We observed staff checking a patient details and gaining written consent appropriately at the start of their transvaginal procedure and signing the patient consent form.

Are diagnostic imaging services caring?

Good 

We have not previously rated this service. We rated it as **good**.

Compassionate care

- Staff cared for patients with compassion, dignity and respect.
- Feedback from four patients confirmed that staff treated them with kindness and understanding. One patient said, 'The lady carrying out the scan was so polite, caring and patient. She explained everything clearly to me' and the other patient told us the staff were 'exceptionally professional and reassuring'.
- We observed how a sonographer introduced themselves to a patient by name and explained the procedure to them. The patient was given an opportunity to ask any questions. They were observed being kind, respectful and helpful.
- We observed how staff ensured that when an intimate procedure was being carried out by a member of the opposite sex, the patient was offered the option of a chaperone. The patient was provided with additional paper covering to maintain their dignity during a scan of intimate areas.
- The manager and sonographer showed compassion and care when they told us about responding to patients who had required an urgent scan. The pathway would alert them to request that a patient made an appointment with their GP where something 'abnormal' on the scan was seen. Sometimes patients responded with distress and they were able to provide support in these circumstances.
- The service monitored feedback from patients through a patient satisfaction survey which was carried out on a continuous basis. Patients were given the option to complete the questionnaire at the end of each patient appointment. An annual patient satisfaction report was planned to be produced for each diagnostic unit based on feedback from patients who used their services. We

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reviewed the feedback summary from 20 patient surveys. Across all age ranges from 20 to 80 years patients were positive about the overall service they had received.

- The provider told us they recognised the need for a compassionate approach when delivering their services knowing patients could be at their lowest emotionally, physically and psychologically when unwell and not diagnosed or treated.
- We observed a patient's dignity being maintained with the use of a privacy curtain and a lockable door in the consulting room.
- We read five thank you cards which commented on the kind staff and the care they had received.

Emotional support

- Staff provided emotional support to patients to minimise their distress.
- The service displayed notices in the reception area to offer patients a chaperone if they wished to have one. The letter that was sent out to patients included information about the use of a chaperone, relation or friend with you during the scan.
- One sonographer told us that patients sometimes showed some anxieties around having a transvaginal scan. They felt they always had the time to reassure and to explain the procedure to patients.

Understanding and involvement of patients and those close to them

- Staff involved patients and those close to them in decisions about their care and treatment.
- Two patients told us their procedures had been fully explained to them.
- One patient explained they had been told what the next stage in their treatment plan was. Their GP had received their scan result within 48 hours and they were being referred on to a specialist consultant.
- Translation services, leaflets and information was available for patients who spoke other languages.
- The services information leaflet provided patients with a brief description of the ultrasound imaging scans available. The leaflet included some information that did not accurately reflect the services currently provided. This was raised with the manager who told us this would be amended.

Are diagnostic imaging services responsive?

Good 

We have not previously rated this service. We rated it as **good**.

- Service delivery to meet the needs of local people.
- The service planned and provided services in a way that met the needs of people.
- The provider had worked with commissioners to deliver services to NHS organisations, providing a community based mobile ultrasound service. The service has a triage system led by a clinician, which enabled correct allocation of a specialist sonographer, based on the patient's clinical history provided by the referrer and presenting symptom history. Once patient clinical information had been cleared, referrals were forwarded as urgent or non-urgent. Patients requiring urgent referrals were offered an appointment within 24 hours for the first available appointment at the nearest or chosen location. Non-urgent referrals were also treated as important and offered appointments in line with patient choice.
- The service offered appointments in the afternoon and evenings, and at weekends, to make it accessible to people at work. For patients referred by their GP, the service offered fast access to a range of ultrasound scans. One patient told us their scan was made available within 48 hours of referral and was close to their home, 'It was an outstanding service for me'.
- For urgent requests and to report any abnormal findings, the provider could ring the GP straight away to give initial findings or provide advice to the patient to go to see their GP. The provider had a process in place for reporting abnormal findings.
- The advanced technical support available, enabled the provider to follow up images and reports to referrers or specialists during the patient's clinical care journey at primary or secondary care locations.

Meeting people's individual needs

- The service took account of patients' individual needs.

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- The referral forms prompted the referrer to identify if the patient had any disabilities that staff needed to take account of. In addition, the appointments letter again asked if patients had any additional needs or disabilities.
- The administrative staff advised patients of how to prepare for their scans when agreeing the appointment including providing patients with preparation advice on nutrition and fluids for the type of scan to be undertaken.
- The service had access to translation services for those patients that did not speak English as a first language, or who were deaf.
- The service offered a choice of appointments, including time and location to suit patients, this included out of normal working hours. Patients were allocated sufficient time at each appointment to allow them time to ask questions. We observed one patient and spoke with three others who told us they were not rushed.
- A sonographer told us how they would support patients who may have additional support needs. They told us it may be people with a learning disability, children or people with a physical disability. They may require a longer appointment time to support their needs. The sonographer told us how a patient had given them a hug as they were appreciative of the patience they had demonstrated to keep them comfortable during the procedure.
- During the booking in process patients were given specific instructions on how to prepare for their scan; for example, bladder scans where they might need to drink extra water. The request form included asking patients if there were other things they needed to adjust for including allergies/sensitivities/disabilities and communication.
- As the clinics were held in GP practices, the locations had disability access.
- The triage process eliminated any form of discrimination based on age, disability, gender, gender reassignment, pregnancy and maternity status, race, religion or belief and sexual orientation based on data provided on referral as it determined patient clinical need based on the clinical information.
- People could access the service when they needed it. The waiting times from referral to treatment were in line with good practice. Information we reviewed showed the provider had not breached any six-week referral to treatment times within the last 12 months.
- Between January 2018 and January 2019, the provider had met, or exceeded its commissioning targets. We looked at indicators from four commissioners which showed that no patients waited over six weeks from referral to treatment and appointments had taken place within 10 days of the date of the referral.
- In agreement with the clinical commissioning groups, clinics were scheduled to meet the demand for the service within each area. Weekend clinics were held where there was sufficient patient demand providing flexibility for patients that required a weekend service.
- Appointments were stored on a shared patient electronic records system in areas where the service had access to such systems. All appointments were confirmed to patients by text message or by letter. The provider accepted online and email referrals for appointments from GPs that did not have access to the shared system.
- Four patients we spoke with told us their appointments were scheduled very speedily with minimal waiting time.
- The provider had a protocol in place for managing patients who did not attend their appointments on an individual basis. Patients who did not attend appointments were contacted within 48 hours to ascertain a reason and were then offered another appointment. Any patients who did not attend the second appointment were discharged back to their original referrer. Two staff members told us they were aware of the potential for safeguarding implications related to repeat non-attendance.

Learning from complaints and concerns

- The service treated concerns and complaints seriously, investigated them and learned lessons from the results, and shared these with all staff.
- The service had a complaints policy that set out the process for how formal complaints would be dealt with. The complaints process was displayed on the wall in the waiting area at the main office.
- The company website included a complaints section for any complaints to be directed to.

Access and flow

- People could access the service when they needed it.

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- A patient guide was made available to patients which gave a synopsis of the processes available to a potential complainant. This directed patients to a more detailed leaflet entitled "Your Guide to making Comments and Complaints". This explained in detail the Harmonic Medical Sonography complaints process which was made available within venues where clinics were held.
- The service had received two complaints within the period from August 2018 to January 2019, both through the formal process and neither were upheld. The four patients we spoke with told us they had no complaints to raise about the service they received.
- Patients could complain through the NHS complaints procedure and information provided advised them of this.
- Complaint outcomes were reviewed at the senior review group meeting and information on complaints was forwarded to the clinical governance committee for review. Learning from complaints was shared at staff meetings. The minutes confirmed this.
- The staff we spoke with knew how to access and record a complaint on the provider's complaint form and to inform the manager.
- The service's complaints process included informing complainants to contact the Care Quality Commission. However, the Care Quality Commission is not a complaints adjudicator and was incorrectly referenced in the complaints policy.

quality, accurate, safe and easily accessible diagnostic scanning and screening service. The ultrasound staff at the satellite clinics were directly managed by the registered /clinical manager.

- The manager was an experienced sonographer who performed high quality ultrasound scans for a wide range of clinical problems. The manager had a broad medical imaging history.
- The manager was a guest lecturer for ultrasound courses at certain universities and presented lectures on musculoskeletal ultrasound to various professional groups that included, sonographers, radiographers and healthcare assistants, physiotherapists and podiatrists as well as GPs interested in musculoskeletal ultrasound.
- The sonographers were able to work in different clinical environments operating a variety of equipment, including transvaginal probes on both static and portable machines. The registered manager told us they kept up to date with the industry; reviewed the British Medical Ultrasound Society's website for updated information, delivered lectures and attended professional conferences.
- At the time of the inspection the registered/clinical manager was supported by a business development director and a sonography practitioner. We were told the manager was recruiting for a consultant radiology/sonographer advisor at the time of the inspection and the business operations director was currently absent from the service. The registered manager was currently in clinical practice as a sonographer. In addition, they were the governance and safeguarding lead for the service.
- Staff told us the manager was 'exceptionally supportive', they were visible and accessible.
- The provider had recruitment and selection policy, which was last updated in September 2018. The policy stated that 'employees are assessed and selected by objective means ensuring that we recruit people with the right skills, knowledge, behaviours and competence to fit the requirements of the role as well as adhering to all relevant legislation'.
- We reviewed three staff files and discussed the recruitment process with two staff including

Are diagnostic imaging services well-led?

Good 

We have not previously rated this service. We rated it as **good**.

Leadership

- Managers of the service had the right skills and abilities to run the service.
- The manager had the right skills and experience to run the service. The manager was focused on providing a

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managerial and administrative staff. We found some shortfalls in records held in paper files; for example, the shortfall in passport photographs, training records. However, the manager told us they were in the process of reviewing and updating the staff files to ensure copies of all relevant documents were held. Training records were later sent to the Care Quality Commission.

- Staff meetings and planning days were held each Monday. Minutes showed these meetings discussed several items including new policies and guidelines, planning and scheduling for clinics, infection control and any lessons learned from complaints.

Vision and strategy

- The service had a vision for what it wanted to achieve and workable plans to turn it into action, which it developed with staff, patients, and local community groups.
- The clinic had a vision for what it wanted to achieve. Staff were aware of the future for the service and how it may develop.
- The provider's mission statement, from their statement of purpose, was to 'achieve the highest possible standards of excellence in screening and diagnostic services'. The sonographer we spoke with was committed to providing a high-quality service for patients.
- Three staff we spoke with were aware of the provider's vision and values. The provider aimed to achieve its vision by providing, 'high quality medical sonography services to patients through their primary healthcare facilities as well as tertiary NHS institutions'. This was confirmed in the company's business plan.

Culture

- There was a positive culture across the service.
- The manager promoted a positive staff culture that valued and supported the staff. There was a sense of a common purpose based on the main objective of providing easy access to high quality medical sonography services to patients through their healthcare providers.
- We observed there was a positive staff culture of being open and honest. The two administrative staff and the

sonographer spoke positively about the leadership of the service and told us there was a commitment to their learning and development. The staff were proud of their work.

- Staff told us patient confidentiality was well respected.

Governance

- The service systematically improved service quality and safeguarded high standards of care by creating an environment for excellent clinical care to flourish.
- The service had an identified governance lead and held governance meetings quarterly. We reviewed the minutes of the meetings of May, July and November 2018. There were some standard agenda items discussed including; incidents, complaints, safeguarding and infection control. During these meeting any audit results, updates to policies and procedures and clinical practice issues were raised. The service had a system in place to ensure that its policies were up to date, regularly reviewed and referenced current guidelines.
- The provider had a range of policies, procedures, and care pathways which covered both clinical and non-clinical issues of the business. Policies referred to, and provided links to, relevant legislation and guidance.
- Policy and procedure documents were stored centrally on the provider's shared information system. We reviewed a range of policies during the inspection and found them to be up to date; however, some of these included information or detail that was not always relevant to the service provided. For example, the infection and prevention policy included the use of sharps and their storage. This was not relevant to this service.
- The manager told us there were weekly staff meetings which we saw the minutes for. These meetings discussed work scheduling, planned audits and any current issues.
- At the inspection we identified the manager did not consistently monitor the staff training so they can maintain an overview of this. There was no protocol in place to clarify which specific training was relevant for clinical and non-clinical staff. This was because the

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policy had not been fully developed. We raised this with the manager at the time of the inspection and the service has been positive in its response to our concern.

- The policy defined induction processes; mandatory training required and the roles and responsibilities of staff at various levels within the organisation. In addition, the policy provided the manager and staff with guidelines to ensure that all staff adhered to their mandatory training requirements each year and detailed the reporting and monitoring processes to ensure that the policy was followed. The manager had created a list to show when staff were due to complete a training refresher course, so this could be monitored.
- At the time of this inspection the provider was in the process of recruiting for a consultant radiologist /sonography practitioner to sit on their clinical governance committee to provide independent oversight.
- All employees had an enhanced disclosure and barring service check in place. Recruited staff provided references and a curriculum vitae. Staff files also included a job description and a signed employment contract. The sonographers provided evidence of their qualifications and training. Two staff files held a photocopy of a photograph rather than an actual passport sized photograph, the manager told us they would address this.
- Any complaints, incidents and audits were discussed at the quality governance meeting held quarterly. The minutes confirmed this.
- The manager had a quality assurance process for reporting images. The manager showed us the process. The sonographer images and reports produced were audited and marked against current standard sonography guidelines.
- We were told that since the inspection the provider has commissioned an external ultrasound company composed of academics, practitioners and a consultant radiologist, who will commence audit activities within the next three months.

Managing risks, issues and performance

- The service had good systems to identify risks, plan to eliminate or reduce them, and cope with both the expected and unexpected.
- The provider had an adverse incident reporting policy issued in January 2018 and for review July 2019.
- We saw the service's risk register. The risks that were monitored included the use of display screen equipment, lone working, privacy in treatment rooms, and a faulty ultrasound machine. The risks were up to date, reported and included timescales for when they were to be removed. Environmental risk assessments were in place for each satellite clinic.
- As part of an equipment safety feature, the scan machines had inbuilt batteries to enable the practitioners to finish their scan and to save the images.
- The service showed improvement as they recognised a need to make sure patients attending for bladder scans had drunk enough water. The minutes of a clinical meeting showed where the manager had audited this and then made improvements to the information that was given to patients prior to bladder scans to prevent them having unsatisfactory scans results.

Managing information

- The service collected, analysed, managed and used information well to support all its activities, using secure electronic systems with security safeguards.
- They collected, managed and used information well to support its activities at all its clinics.
- Patient data and appointments were managed centrally by the provider using a secure electronic record system. Patient scan images and reports were initially stored locally on the ultrasound scanner before secure encrypted transmission to the provider's central records systems.
- The portable ultrasound scanners required the user to input a password when switching the machine on, therefore access was restricted to confidential patient information stored on the machine. In addition, machines were securely stored.

Engagement

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- The service engaged well with patients, staff, the public and local organisations to plan and manage appropriate services, and collaborated with partner organisations effectively.
- The staff were keen to engage their patients and improve the patient experience. Reviews of the service included a patient experience questionnaire. Patients had an opportunity to review and comment on the service they received. Blank patient surveys were kept on the reception desks and given to patients on discharge.
- Data gathered from the patient satisfaction questionnaire was produced and discussed at staff meetings to identify any gaps in service delivery and ways to improve. We saw data from the previous quarter which was all positive.
- The average was 98% for service users reporting a high level of satisfaction of the service, indicating they were either 'likely' or 'very likely' to recommend the service.

Learning, continuous improvement and innovation

- The service was committed to improving services by learning from when things went well or wrong, promoting training and innovation.
- The provider was working towards accreditation by the United Kingdom Accreditation Service which gives formal third-party recognition that an imaging services provider has demonstrated their organisational competence to deliver high quality imaging services.
- The provider had been challenged in accessing the GPs and NHS providers to share images. The provider had developed and worked with external providers to identify software regarding storage of data and their system was now corrected so they could send images.
- Sonography practitioners were encouraged to attend professional courses. For example, one sonographer was attending a specialist course in musculoskeletal ultrasound.

Outstanding practice and areas for improvement

Areas for improvement

Action the provider **SHOULD** take to improve

- The provider should review its services leaflet to accurately reflect the services it provides.
- The provider should consistently monitor staff training so they can maintain an overview of this when staff were due to complete a training update.
- The provider should monitor the cleaning checklist for the general housekeeping to ensure this is carried out.
- The provider should review the policies to include information and detail relevant to the service provided. For example, the infection and prevention policy included the use of sharps and the storage of sharps which is not relevant to this service.
- The provider should review the staff records and include an actual passport sized photograph of each staff member recruited, rather than a photocopy of a passport photograph.
- The provider should confirm the recruitment of a consultant radiologist /sonography practitioner to sit on their clinical governance committee to provide independent oversight.
- The provider should review the service's complaints process which currently informs complainants to contact the Care Quality Commission as the Care Quality Commission is not a complaints adjudicator.