Ultrasound Direct Ltd

Quality Report

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Date of inspection visit: 14 to 23 August 2018
Date of publication: 19/10/2018

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?	
Are services caring?	Good
Are services responsive?	Good
Are services well-led?	Good

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.

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

Ultrasound Direct Ltd is operated by Ultrasound Direct Limited. The service had one registered location with 32 satellite clinics located around England. Two satellite clinics was based in Ireland (Belfast and Newry).

The service provides diagnostic imaging services (ultrasound scans) to the local community. We inspected diagnostic imaging services at this location and a selection of satellite clinics.

We inspected this service using our comprehensive inspection methodology. We carried out an unannounced inspection on 14 August 2018 and six short notice announced visits to satellite clinics across England between 15 August to 23 August 2018.

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.

The only service provided at this location was diagnostic imaging.

Services we rate

We previously did not have the authority to rate this service, however we now have the authority to rate these services. We rated it as good overall.

We found the following areas of good practice:

- There was a system and process in place for identifying and reporting potential abuse. Staff could provide examples where they had needed to escalate concerns.
- The service had a positive approach to learning from incidents and complaints. They reviewed all incidents regardless of level of harm and complaints to identify if any learning opportunities were evident.
- There was a robust process in place for the escalation of unexpected findings during ultrasound scans. The service had developed links with local acute healthcare providers to enable a seamless onward referral for patients experiencing complications with pregnancy, as well as a well embedded referral process for non-pregnancy related complications. We saw examples of staff escalating unexpected findings during our inspection.
- There was a proactive approach to training and continuous professional development for staff who worked at the service. The introduction of the Ultrasound School was an innovative way of ensuring staff remained clinically up to date and competent whilst giving staff the opportunity to develop new skills and competencies.
- Patients were cared for by clinically competent and professionally adept staff. The service took competency seriously and the processes for overviewing competency seriously and had entered staff with no professional registration on to the Society of Radiographers register.
- Feedback from patients was overwhelmingly positive during our inspection and we observed some examples of high quality care and treatment provided to patients. Patients were engaged with and encouraged to be partners in their care and treatment provided.
- Clinical environments were visibly clean and tidy, and were suitable and appropriate to meet the needs of the patients who attended for appointments, as well as relatives and children who accompanied them.

Summary of findings

- Appointments were scheduled to meet the needs and demands of the patients who required their services. Throughout the regions which the service covered, they had arranged for seven-day services to be available, with a wide range of appointment times to suit patients. Same day appointments were also available for patients who required them.
- The vision and values were understood and well embedded in staff's daily work. Staff felt supported by a leadership team who were credible, approachable and visible. Staff were proud to work at the service and there were high levels of satisfaction across all staff groups.
- There were governance systems in place to monitor the high-quality and sustainable care being provided to patients.
- The service had systems in place to acquire feedback from staff and patients to enable them to continually improve the service being provided.

However, we found areas of practice that the service needed to improve:

- We found issues regarding the environment of some of the clinical locations which did not fully support good infection prevention and control practices. Some locations did not have a handwashing sink immediately available for staff and some locations had carpeted floors in the ultrasound scanning room.
- The clinical assistant staff group had not previously been required to complete mandatory training. Senior management had recognised this as an issue and had implemented a training programme for all clinical assistants to complete. This programme was due for completion by November 2018. We saw this was on trajectory at the time of our inspection.
- The service had minimal processes in place to demonstrate patient outcomes. Senior management had already identified this and had recently implemented an annual audit programme and audit meeting for oversight of this.
- The human resources (HR) process were being changed to a new system at the time of our inspection, this made viewing staffing files difficult. The staff files we did review were not all complete, however some of this was related to the transfer from the old HR system to the new.

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

Heidi Smoult

Deputy Chief Inspector of Hospitals (Central)

Summary of findings

Our judgements about each of the main services

Service	Rating	Summary of each main service
Diagnostic Imaging and Endoscopy Services	**Good**	The provision of ultrasound scanning services, which is classified under the diagnostic imaging and endoscopy core service was the only core service provided at this service. We rated this core service as good overall because patients were protected from avoidable harm and abuse. Care and treatment was provided based on best practice and provided by competent staff. Feedback from patients was positive and we ourselves observed positive examples of compassionate care. Patients could access care and treatment in a timely way and there were flexible appointment times to meet patient needs. There was strong leadership team who provided values based vision and strategy which staff were aware of and aligned with. Governance processes were in place to provide adequate assurances of service provision and drive improvement.

Summary of findings

Contents

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Ultrasound Direct Ltd

Services we looked at:

Diagnostic Imaging and Endoscopy Services

Summary of this inspection

Background to Ultrasound Direct Ltd

Ultrasound Direct Ltd is operated by Ultrasound Direct Limited. The head office location at Market Harborough, Leicestershire opened in February 2015, however the provider registered in October 2010. The service has provided pregnancy scanning services since 1998 (Babybond scans). Since this, the service has evolved and now offers non-invasive prenatal tests with some early pregnancy related scans, well women and well men ultrasound scans and ultrasound scans for musculoskeletal conditions. The service also completes non-obstetric ultrasound scans as part of a subcontract for the NHS.

The service provides ultrasound scanning services for people aged 16 years and above.

The service has had a registered manager in post since registering with the CQC in October 2010.

Our inspection team

The team comprised of a CQC lead inspector and an assistant inspector who had both completed the single speciality diagnostic imaging training. An additional five CQC inspectors and one inspection manager supported visits to satellite clinics. The inspection team was overseen by Simon Brown, Inspection Manager.

Information about Ultrasound Direct Ltd

The registered location was registered to provide:

- Diagnostic and screening procedures.

During the inspection, we visited the registered location at Market Harborough as well as six satellite units in, Birmingham, Derby, Kettering, Market Harborough (St Luke's Hospital), Nottingham and Romford. We spoke with 15 staff including; registered midwives, clinical assistants, administration staff, sonographers and senior managers. We observed 25 ultrasound scans and engaged with patients and relatives during these procedures. During our inspection, we reviewed 16 patient records.

There were no special reviews or investigations of the service ongoing by the CQC at any time during the 12 months before this inspection.

This was the first inspection of the service since the most recent update to the registration in August 2017. The service has previously been inspected in 2012 and 2013 prior to the changes to the service name and location of services.

Activity (August 2017 to July 2018)

- There were 126,372 ultrasound scans performed at the service; of these 99% (124,967) were privately funded and 1% (1,405) were completed as part of a NHS sub-contract for non-obstetric ultrasound scans.
- Of the 124,967 privately funded ultrasound scans, 92% were scans of pregnant patients, 6% were well women scans and 2% were well men scans.

Eighty-nine sonographers and 57 clinical assistants worked at the service on a sessional (as required) contract. The service directly employed 11 sonographers nine of which were also in managerial positions, seven clinical assistants and 12 additional staff including the directors, head office management and administration staff. The service did not use any medicines and therefore they did not have an accountable officer for controlled drugs (CDs).

Track record on safety

- There were no never events
- There were no serious events
- Six clinical incidents all of which were no harm.

Summary of this inspection

- One hundred and seventeen complaints, eight of which were upheld.

Services accredited by a national body:

- The service currently had no accreditations by national bodies.

Services provided under service level agreement:

- Clinical and or non-clinical waste removal
- Laboratory services
- Interpreting services
- 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?

Good

We rated safe as good because:

- There was a robust safeguarding process at the service and staff knowledge was also positive. Staff could provide examples of how they had identified and handled previous safeguarding concerns.
- There was a process in place for staff to follow when escalating unexpected findings from the procedures. Staff were knowledgeable of this process and could give examples of when they had needed to do this.
- All practitioners completing pregnancy related scans believed they had a professional responsibility to complete well-being checks of the baby prioritising this over the souvenir scanning which took place.
- Mandatory training levels for managerial staff, administration staff and sonographers was recorded at 100% against their internal target of 100%.
- The service had a positive safety track record. There were no reported never events or serious incidents and there was a low number of incidents reported by staff.
- There was an incident reporting policy and procedure in place which all staff were aware of. The service had a positive approach to incident reporting and learning from all incidents, regardless of level of harm.

However, we also found

- There was a lack of handwashing sinks in some of the satellite clinics, with the nearest available sinks being some distance away from the scanning room in some locations. However, the provider had ordered portable sinks for all these locations and were awaiting delivery.
- There were carpeted floors in some of the clinical locations. Staff were aware of the risks and tried to mitigate the risk during clinical activity until modification of the environment could take place.
- Clinical assistants (both salaried and sessional) had not previously been required to complete any of the mandatory training topics. Senior staff had identified this as an issue and had implemented a training programme for this staff group which was due to be completed by November 2018. At the time of our inspection, 16% of clinical assistants had completed the training programme.

Summary of this inspection

Are services effective?

We do not rate effective.

- Sonographers who were not on a professional register (HCPC or NMC) were entered on to the Society of Radiographers voluntary register.
- Staff were knowledgeable of the consent process including issues which may impact on consent (MCA and Gillick competency).
- Staff ensured all patients who attended for pre-natal testing received counselling prior to the test and gained formal consent.
- Policies, procedures and guidance was based on national policies, legislation and best practice guidance including those released by bodies such as National Institute for Health and Care Excellence (NICE), the British Medical Ultrasound Society, Royal College of Obstetricians and Gynaecologists and the Society of Radiographers.
- The service had a positive approach to providing staff with training and continuous professional development (CPD) opportunities. The service had developed their own Ultrasound School which had technology to enhance and develop staffs skills and competencies.
- We observed multidisciplinary staff including the external stakeholders working positively with each other, and the feedback from external stakeholders was positive.

However,

- At the time of our inspection, the service had little evidence to demonstrate patient outcomes. An audit programme had only just been implemented prior to our inspection.

Are services caring?

Good

We rated caring as good because:

- Patients we spoke with were all positive about the service they received and the staff who provided the service.
- We observed 25 episodes of care during our inspection and all were extremely positive. Staff were compassionate, respectful and provided appropriate emotional support to patients who required this.
- Staff ensured patients received relevant information about their ultrasound scan and gave patients many opportunities to ask questions if they needed further explanation. Language and terminology was adapted to the patient involved to ensure they understood.

Summary of this inspection

- The service had invested in the staff by providing specific training to ensure they were prepared to deliver bad news and could provide the appropriate support to patients.
- There were systems in place for the service to receive feedback from patients on a regular basis. Feedback received from patients was largely positive.

However,

- Clinical assistants provided a chaperone role if patients requested one or the ultrasound was of an intimate nature, however they had received no specific training to act as a chaperone.

Are services responsive?

Good

We rated responsive as good because:

- The clinical environments were suitable and appropriate to meet the needs of the patients.
- The service ensured there were appointments available to meet the needs of the patients. Clinics were organised to ensure availability in all regions was seven days per week, with a range of appointment times.
- There was an opportunity for patients to receive a same day appointment if they contact the service by telephone.
- Interpretation services were available for patients whose first language was not English.
- The service had a positive approach to the complaints they received and the management of complaints. There was an operational manager who led the complaints handling process.

However,

- All clinical locations had minimal patient information leaflets available for patients to take away. The leaflets that were available were only available in English with no variation in print size for patients who may be visually impaired.

Are services well-led?

Good

We rated well-led as good because:

- Staff were complimentary about the leaders of the service. Immediate leaders were approachable, visible and supportive to staff. Senior management were relatively visible considering the geographical spread, but all staff said they were approachable.
- There was a positive culture amongst all staff. Staff enjoyed working for the service and would recommend this as a place to work.

Summary of this inspection

- There was a vision and strategy in place which staff were aware of and aligned to.
- Governance systems were in place which all staff were aware of and involved in. There was evidence of information and issues being escalated upwards, as well as information being cascaded downwards through the system.
- There was a process in place to identify and assess risks in the service, with ongoing monitoring of them through the governance system.

However,

- We found staff files did not contain all the required documentation under schedule 3 of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014. However, the service was undergoing a change in human resources systems at the time which impacted on the ability to review staff files.

Detailed findings from this inspection

Overview of ratings

Our ratings for this location are:

	Safe	Effective	Caring	Responsive	Well-led	Overall
Diagnostic Imaging and Endoscopy Services	Good	N/A	Good	Good	Good	Good
Overall	Good	N/A	Good	Good	Good	Good

Notes

Good

Diagnostic Imaging and Endoscopy Services

Safe	Good
Effective	
Caring	Good
Responsive	Good
Well-led	Good

Are diagnostic imaging and endoscopy services safe?

Good

We previously did not have the authority to rate this service. However, on this inspection we did have authority to rate and we rated it as good.

Mandatory training

- The service had a mandatory and statutory training requirement which all salaried staff and sessional sonographers had to show evidence of completing. The topics included were equality and diversity, health and safety at work, Control of Substances Hazardous to Health (COSHH), Caldicott principles, fire safety awareness, infection control, information governance, manual handling, basic life support, safeguarding vulnerable adults, safeguarding children level one and two, conflict management and lone working. The compliance target for mandatory training was 100%.
- All 'salaried' staff (those directly employed by the provider) had completed their mandatory training. Regional managers were required to attend a meeting twice per year where mandatory training modules would also be completed and recorded.
- The service employed 89 'sessional' sonographers who were primarily employed elsewhere. The mandatory training completed in their usual place of work was transferrable to this service and all staff had a record of what mandatory training had been completed. At the time of our inspection, 100% of sessional sonographers were in date for the mandatory training. We were told that staff were required to provide evidence of their updated mandatory training at their appraisal.
- At the time of our inspection, not all clinical assistants had completed mandatory and statutory training. Compliance with mandatory and statutory training for this staff group was 16%. Senior staff told us there was a programme in place for all clinical assistants to complete the training by November 2018 which was on trajectory for completion.

Safeguarding

- The service had a safeguarding adults policy in place which was dated January 2013. The policy provided staff with information about what constitutes abuse and advice on what to do in the event of a concern. The policy however referred to the now outdated document 'No Secrets' instead of The Care Act 2014 which sets out the statutory responsibility for staff regarding safeguarding. There was also no review date documented on the policy so we were not assured the service updated this policy to reflect current guidance.
- The service had a safeguarding children policy in place for staff to follow which was dated November 2017. This policy had details of the lead for safeguarding as well as a named sonographer for safeguarding children. The policy also contained detailed information about specific risks for staff to be aware of when providing care and treatment to children, or if providing care and treatment whilst children were present.
- Staff had a knowledge of safeguarding vulnerable adults and children and were aware of who the leads

were and the escalation process for when concerns were identified. During our inspection staff told us there had been three safeguarding concerns raised, two of which had been since the pre-inspection information request had been sent. Staff described the incidents and the actions taken and the escalation process had been followed appropriately.

- The service performed ultrasound scans for patients from the age of 16 years old. Staff were trained to level two in children's safeguarding, but had access to managers who were level three trained and the escalation system ensured there was a seamless process to inform the relevant agencies. This was in line with national requirements as sonographers were only responsible for recording the ultrasound scan pictures and were not involved in the planning and implementation of care after this. Staff had told us patients under the age of 16 had attempted to be scanned, but their checking processes ensured no patient under the age of 16 were scanned.
- The training all staff received included female genital mutilation (FGM). Female genital mutilation/cutting is defined as the partial or total removal of the female external genitalia for non-medical reasons. Since October 2015, it is mandatory for regulated health and social care professionals to report known cases of FGM, in persons under the age of 18, to the police. There were four types of FGM which healthcare professionals are required to report. The safeguarding children policy contained details for staff about FGM as well as honour based violence and forced marriage. Staff we spoke with were aware of these safeguarding issues and felt confident in identifying concerns and the actions they would take.
- Child sexual exploitation (CSE) training was not part of all staff safeguarding training and was not included in the services safeguarding children and young people policy. The lead for safeguarding children at the service as well as one of the other managers were completing more enhanced training and would then share this knowledge with other staff. Despite not all staff having formal CSE training, we found that staff in the clinics had a good understanding of CSE and what to look for. Staff were aware of local cases of CSE which had raised the profile of such abuse and the signs to look out for.
- All staff we spoke with were aware of the concerns around domestic violence. In many of the satellite clinics, posters were displayed in female toilets which highlighted this concern and gave women details of how to seek out further support if required. Staff did comment however about the inequality of this and how there had been an increase in domestic violence against men. Staff were aware of the signs to be concerned about in both sexes and would feel confident to support anybody in seeking further support if required.
- The service did not have a formal system in place where alerts for known safeguarding concerns could be activated. However, following the recent safeguarding concern, staff used the booking system to enter additional safety details for when the patient return for a follow up ultrasound scan.

Cleanliness, infection control and hygiene

- All the clinical environments that we visited during our inspection were found to be visibly clean and tidy. All areas had evidence of a cleaning schedule which was signed when staff had completed the cleaning duties.
- The service had close links to an infection prevention and control specialist from another provider, however they were in the process of providing training to a member of their own staff to perform the role of a link practitioner.
- Not all clinical areas had access to a handwashing basin in the room. The service was aware of this risk and had ordered portable sinks for areas where a plumbed in sink was not available. At the time of our inspection, there was a delay on the provision of these portable sinks due to manufacturing problems. Staff told us although they did not immediately have access to a handwashing basin, there was usually one nearby which they could use. Staff did however have access to alcohol hand gels which they used to decontaminate their hands. We observed staff using alcohol hand gels in accordance with the World Health Organisations (WHO) five moments for hand hygiene.
- The majority of staff we observed in clinical environments were 'bare below elbow'. However, in some clinical areas, we did observe staff who had direct patient access who did not adhere to this as they were wearing stoned rings and had painted nails.

- At the time of our inspection, the service had not completed hand hygiene audits within the clinical locations, however now there was a new IPC link practitioner for the service these would be commencing.
- We observed staff decontaminating the equipment after use. Staff currently used a spray product which was recommended by the equipment manufacturer, however they were imminently moving over to a different product which was also highly recommended in ultrasound probe decontamination.
- Staff had access to personal protective equipment (PPE) in the clinical environment. We observed staff undertaking intimate examinations using gloves and aprons during these procedures. Staff told us they regularly had additional PPE supplied to them to ensure they always had access to this when required.
- Staff used paper towel to cover the examination couch during a scanning procedure. We observed staff changing this in between each patient.
- Staff had been trained up to perform venepuncture (blood taking) for certain pregnancy related blood tests. Staff told us the training included the principles of aseptic non-touch technique (ANTT) and they were required to complete supervised procedures before being allowed to complete the task on their own. We observed staff completing this procedure however, not all staff adhered to the principles of ANTT as not all staff wore PPE whilst completing the task.
- We observed carpets on the floors in some of the clinical satellite locations. Staff were aware of the risks this presented and ensured they covered the immediate area when completing any blood taking procedures. Senior staff were aware of this risk and had mitigating actions in place until modification to the environments could be made.
- The service offered pregnant patients screening for Group B Streptococcus (GBS). GBS is a bacteria (bug) which can be carried by women in the vagina and not cause harm to them. However, this can be passed on to a baby during child birth and may cause infection. Staff told us uptake of this screening was more popular in some clinics than others, however there was an intention to maintain this option for patients to ensure they had access to a wide range of screening.
- Blood samples were packaged up and sent to the laboratory using the technique and materials as directed by the laboratory. This ensured the service complied with the relevant legislation and guidance which covers the transportation of infectious substances.

Environment and equipment

- The service did not have resuscitation equipment in any of the clinical areas, although in some of the areas where clinics were held, there was access to defibrillators which were provided by a third party.
- All electrical equipment we inspected had been checked annually as per safety recommendations. However, as there was a large proportion of new ultrasound scanning machines in use, these did not have evidence on the actual item to identify they had been tested for electrical safety. The information to demonstrate this was provided on their installation documentation.
- All servicing of the electrical equipment was completed by external companies. Staff were aware when the next service was due. However new items of equipment did not have any stickers to indicate when a service was next due, this information was provided on the installation documentation.
- The service maintained a log of when equipment was not working and the length of time the equipment was out of order. Within this document was also the reason for the equipment being out of order and the actions taken to resolve the issue. There were five entries made on this log between August 2017 and June 2018. Four of these occurrences did not impact on patients, with the remaining one incident having minimal impact on patients.
- Staff told us they had sufficient amounts of equipment to complete their jobs and the equipment they had was of a decent quality compared to other places they had worked.
- We observed staff segregating clinical and domestic waste correctly in most areas, into waste bins which were enclosed and foot operated. However, in some of the clinical locations, we did observe staff placing clinical waste into a non-clinical waste bag. Staff were aware of the different waste streams; however, they

did not have access at the time to the correct coloured bags. Sharps bins were correctly assembled and below the fill line, however we found the details on the sharps bins had not always been completed. The management and disposal of sharps and waste was completed in accordance with policy by an external company.

Assessing and responding to patient risk

- The service had a process in place for the management of patients who suddenly became unwell during their procedure. In the event of a cardiac arrest, staff called 999 for an ambulance. Staff were trained in basic life support and would put their training into use until the ambulance arrived. Since the service started, staff reported no incidences of having to call for an ambulance.
- All patients who underwent a transvaginal ultrasound scan were asked if they had any allergies to latex. Patients were also asked to sign the form next to this question and to confirm their response. The service had both latex and non-latex covers for the transvaginal ultrasound probe and would select the cover according to the response from the patient.
- The service had clear procedures in place to guide staff on what actions to take if any suspicious findings (whether expected or unexpected) were found on the ultrasound scan they had attended for. Staff were able to give examples where they had to use this process when they identified some unexpected findings on a scan. For patients attending non-obstetric related ultrasound scans, with their permission, they would be advised to return to their GP with a copy of the ultrasound scan report. Staff would also call the GP if the concern was time critical (for example if a suspected malignancy had been identified).
- Patients who attended for ultrasound scans in the early stages of pregnancy, who staff subsequently identified concerns with the fetus or identified the patient was having a miscarriage, had a process of referring the patient to their nearest early pregnancy assessment unit (EPAU) for further assessment and follow up.
- Most patients were eligible for an ultrasound scan at this service. The only exclusion they had was around patients who already had a pre-existing condition and undergoing treatment.
- The service was aware of the British Medical Ultrasound Society and Society of Radiographers 'paused and checked' checklist which is recommended to be completed prior to an ultrasound scan. Senior staff told us they had reviewed the document but found this was not relevant to the vast majority of ultrasound scans they performed.
- All staff we spoke with advised patients who attended the service for pregnancy related scans to continue with their booked appointments with the midwife and ultrasound scans which was part of the antenatal service. Staff made sure patients understood any ultrasound scans which they performed were in addition to the routine care they received. This was because although on each scan they completed a 'well-being' check of the baby, the ultrasound scans were usually for a specific reason, and the ultrasound scans performed during the routine antenatal journey were usually looking for other specific information about the well-being of the baby.

Staffing

- The service had nine managers in post, two of which were national managers and seven were regional managers. All nine managers were sonographers and worked clinically as well having an area of responsibility.
- In total the service directly employed 11 sonographers and had access to 89 'sessional' sonographers who would cover the satellite clinic requirements. The sessional sonographers were permanently employed in other organisations, and completed additional work for the service on a zero hours contract.
- In total, the service had 64 clinical assistants, seven of which were employed by the service and the remaining 57 were on a 'sessional' work basis. Clinical assistants were responsible for administration duties as well as aiding the sonographers with any ultrasound scans and chaperone requirements.
- The service had low vacancy rates at the time of our inspection. Information provided by the service

showed there was one vacancy for the position of clinical assistant manager and one for customer service assistant. Both were new positions that were being recruited for. In addition, there were two positions for sessional clinical assistants available to replace staff who had left.

- Information provided by the service showed between August 2017 to July 2018 there were 33 staff members who had left the service (14 sessional sonographers, 16 sessional clinical assistants, one office administrator, one finance manager and one marketing coordinator). Senior staff told us staff leaving the service mainly did so due to new opportunities. No staff members had left for negative reasons.
- The service did not use locum staff, bank staff or agency staff. In the event of a staff member going off sick, the service did not have any problems with arranging cover. Staff were keen to be flexible and cover any short notice sickness. Staff told us about an example of one staff member who volunteered to work away from their normal area of work to ensure a clinic was fully staffed and ensure the appointments went ahead as scheduled.
- All clinics were staffed with one sonographer and one clinical assistant. The service used a system for scheduling staff for the clinics. Clinics were scheduled three months in advance and staff assigned themselves to the clinics which they wanted to work or clinics which fit around their permanent employment positions. No staff members were required to work as a 'lone worker'.

Records

- The service used a combination of paper and electronic records. Paper records were used by sonographers during the ultrasound scan to record essential information (for example, measurements). A copy of this record was given to the patient at the end of their procedure for them to take with them. The service scanned their copy of this record and kept this on their systems. There were different paper records dependant on which ultrasound scan the patient had requested.
- If staff identified any concerning findings during the procedure, a more detailed report would be produced by the sonographer and if consent given (and recorded on the paper record) this would be forwarded to their GP. Detailed reports for patients were completed and forwarded to healthcare practitioners within 24 hours of the patient's procedure.
- The service completed a records audit to review the quality of the scan images and reporting of the scan in April 2018. The results showed all sonographers were providing scans of reasonable or high quality, and all reports produced were of reasonable or high quality. The author of the report did identify areas which could be improved, however no action plan for addressing these issues was produced.
- We reviewed 16 records during the inspection. The majority of these were paper records and we found staff recorded all the specified information in a clear and accurate way.

Medicines

- The service did not use any medicines for any of their procedures and therefore did not have a medicines policy in place.

Incidents

- There were no never events reported for the service from August 2017 to July 2018. Never events are serious incidents that are entirely preventable as guidance, or safety recommendations providing strong systemic protective barriers, are available at a national level, and should have been implemented by all healthcare providers.
- There were no serious incidents reported for the service from August 2017 to July 2018. Serious incidents are events in health care where there is potential for learning or the consequences are so significant that they warrant using additional resources to mount a comprehensive response.
- The service had an incident policy for staff to follow which was dated March 2017. This guided staff on the reporting procedure for incidents, the grading of incidents and the investigation process expected for the more serious incidents, including the root cause

analysis process. The policy was due to be reviewed in two years from the date of its approval. All staff we spoke with were aware of this policy and the incident reporting procedure.

- The service had recorded six incidents from August 2017 to July 2018. All incidents were graded as no harm, however the service still looked for opportunities to learn lessons from these incidents.
- The service was upgrading their electronic systems at the time of our inspection. Part of these upgrades included incident reporting and recording of lessons learnt. Currently all incidents were reported through the use of a paper form which was handed to their regional manager for investigation. The service had also recently started a learning log for incidents which would be accessible to all staff on this new system when this was implemented.
- Regulation 20 of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014 is a regulation, which was introduced in November 2014. This regulation requires the organisation to be open and transparent with a patient when things go wrong in relation to their care and the patient suffers harm or could suffer harm, which falls into defined thresholds. The duty of candour regulation only applies to incidents where severe or moderate harm to a patient has occurred.
- Staff we spoke with had an understanding of the duty of candour process and the need for being open and honest with patients when errors occur. Senior staff members were able to explain the process they would undertake if they needed to implement they duty of candour following an incident which met the requirements, however at the time of our inspection, they had not needed to do this.
- Senior staff were aware of the requirements for reporting serious incidents to the CQC using the statutory notification route if this met the criteria, under Regulation 18 of the Care Quality Commission (Registration) Regulations 2009.

Are diagnostic imaging and endoscopy services effective?

(for example, treatment is effective)

We do not rate effective.

Evidence-based care and treatment

- We reviewed policies, procedures and guidelines produced for the service to implement locally. These were mainly based on current legislation, evidence-based care and treatment and best practice, which included policies and guidance from professional organisations such as National Institute for Health and Care Excellence (NICE), the British Medical Ultrasound Society, Royal College of Obstetricians and Gynaecologists and the Society of Radiographers. An example of NICE guidance which the service followed was CG154 Ectopic pregnancy and miscarriage: diagnosis and initial management.
- The service used subject matter experts to provide advice and guidance for specific gynaecological and fertility matters through a third party. They had also engaged with these subject matter experts to review specific policies for the service.
- All clinics had access to a policy folder which contained paper copies of all the up-to-date policies staff needed. Staff told us the head office sent out paper copies of policies to place in the folders when they were updated. Some staff also had access to these policies on an electronic system.
- The service had recently identified a gap in their local audit plans. A local audit programme had now been devised and was to be implemented immediately. An audit specific meeting had also been organised to have oversight of the audit programme and the information coming from the audits completed. At the time of our inspection, the local audits which the service completed were cleaning audits, equipment check audits and records audits.

Nutrition and hydration

- There were no nutrition and hydration services for patients that attended for ultrasound scans. However, staff had access to a selection of refreshments (tea,

coffee and water) which they provided patients in some circumstances. During our visit to a satellite clinic, we observed staff providing a patient with a bottle of water as they had started to feel faint.

Pain relief

- Patients were asked by staff if they were comfortable during their ultrasound scans, however no formal pain level monitoring was undertaken as these procedures were pain free.

Patient outcomes

- Regional managers were responsible for completing rescan audits for their areas of responsibility. The results of the audits shared with the CQC showed the most common reason for re-scans was due to the early stage of pregnancy and positioning during four dimensional (4D) scans. The audit presentation included suggested recommendations for improvements prior to the next annual audit.
- The records audit from April 2018 which looked at quality of ultrasound scans produced and the quality of the reports produced by sonographers. The results were broken down into individual sonographer performance rates. All sonographers were producing scans and reports of reasonable or high quality. No sonographer had produced reports or scans of poor quality.
- Senior staff told us they were not required to produce any specific data for identifying patient outcomes for their NHS sub-contract of AQP NOUS (any qualified professional non-obstetric ultrasound scans). However, they did inform us that they forwarded information about waiting times and patients who did not attend (DNA) their appointments to enable the contractors to complete a patient outcome return.
- The service had a local key performance indicator (KPI) which they had to adhere to for the number of ultrasounds performed per hour. This KPI was monitored through the clinical governance meetings.

Competent staff

- At the head office, there was an Ultrasound School which all staff used for training purposes. The school had two ultrasound training simulator machines (a transvaginal and a transabdominal machine) which staff used to demonstrate their clinical currency and competency, as well as developing their skills in sonography. Staff feedback about the school was positive as there were no other services around which offered this level of training support.
- Senior staff told us they had recently used the school as a base for training a member of staff to become a sonographer in conjunction with a local university. Although most clinical practice was undertaken at the service, they had also arranged clinical placements at a local NHS trust to cover areas within sonography which the service currently doesn't provide. The feedback from this had been extremely positive and the service were looking at providing more training opportunities.
- The service offered staff continuous learning opportunities to enhance their current roles. Courses provided included fetal heart scanning, breaking bad news and a range of other fetal courses provided by an external provider. Staff told us the training was extremely well received and had been useful for their role at the service.
- The service had a competency document in place for all new sonographers to complete when joining the service. This competency document focused on the scanning requirements for obstetric, gynaecological, general and musculoskeletal scanning, as well as some local induction tasks which were required to be completed. Senior staff told us the time length for staff to complete these were not specific and down to the individual. Staff would not be expected to start running their own clinics until competencies were signed off and the regional managers had development meetings with staff. We saw evidence of completed competency documents stored on staff's individual files.
- The majority of sonographers were registered with a professional body, either the Health and Care Professionals Council (HCPC) due to previous registration as a radiographer, or they were registered with the Nursing and Midwifery Council (NMC) as the sonographers have a background employment history as a midwife. For sonographers who were not registered with either of these professional bodies, the service had registered them on the Society of Radiographers register.

- The service did not have any formal arrangement in place to ensure they were informed of any performance problems or other concerns leading to action being taken against a staff member, or likewise informing other providers if they themselves had concerns about staff members. Senior staff told us this was all done anecdotally. However, if they did have concerns about a member of staff, they would check the professional register for any indication of concerns.
- Appraisals were completed on an annual basis and once completed, were stored in staff files. Information provided by the service showed 100% compliance for appraisals for national managers, finance and IT managers, administration staff, marketing managers and operational managers. Sessional sonographers currently had an 86% compliance rate with appraisals, 74% of clinical assistants had received an appraisal and 71% of regional managers had received an appraisal. All staff told us these were meaningful and a good opportunity to identify any additional training requirements to enhance their role.

Multidisciplinary working

- During our inspection, we observed and were told about some positive examples of staff working well together. One staff member spoke about a positive experience from a local NHS trust that updated them about a patient they had performed an ultrasound scan on who had undergone a multidisciplinary team meeting at the hospital due to the positive identification of a cancer during a scan.
- All staff members on all levels worked well with each other to ensure patients had a positive experience at the service. Staff told us if there were any shortages of staff in any areas, other members of the team would help out.
- External stakeholder feedback about staff from the service was also positive. The relationship that had been built with the contractors for the AQP-NOUS service had meant that an effective service was now being offered to the patients who were referred for ultrasound scans.
- Staff told us if they identified any findings which required escalation to another health provider, staff would immediately communicate with relevant healthcare professionals (with the patient's consent) and follow this up with a formal report within 24 hours of the appointment. During our inspection, we observed formal reports that had been completed by staff awaiting the administration team to send them on to a designated healthcare professional.
- For patients who were seen as part of the AQP-NOUS sub-contract, staff entered details directly on to an electronic reporting system which is linked to NHS records. Ultrasound images were also uploaded on to an electronic system which could be accessed by NHS healthcare professionals for the purpose of identifying correct treatment decisions.

Seven-day services

- The service was not a traditional seven-day service, as not all satellite clinics opened seven-days a week. However, the service had taken into consideration the requirement for having a range of appointments available to patients and therefore appointments were scheduled to ensure patients could attend a satellite clinic any day of the week in a region.
- The timings that were offered to patients were also arranged to try an ensure all regions had appointments to cover morning, afternoon and evening demand.

Health promotion

- Staff told us they did not routinely have health promotion literature available within the satellite clinics or at the scanning department within the head office. However, we did see information which promoted an external company who offered a service of banking cord blood which could be used in the future for a range of illnesses.
- Staff also told us they had individual social media pages which were open to the public which staff would go on to and complete posts in relation to health promotion.

Consent and Mental Capacity Act

- All staff were aware of the importance for gaining consent from patients before conducting any procedures. Staff told us verbal consent for abdominal ultrasound scans was acceptable, however the service

had separate consent forms for patients undergoing a transvaginal ultrasound scan. We observed staff gaining consent from patients prior to starting their ultrasound scan.

- The service ensured all patients who requested pre-natal screening tests were counselled prior to testing. This ensured staff were satisfied with the patient's rationale for the test and they had considered what the next steps would include if the tests revealed some concerning findings. After staff had discussed this with the patient, patients were required to formally consent to the tests being taken.
- The service had a Mental Capacity Act and Deprivation of Liberty Safeguards policy in place which was dated October 2017. The policy provides staff with information about patients who may lack capacity and when to undertake a capacity assessment. It also provides additional information about best interest decisions, advanced decisions and the role of the independent mental capacity advocates (IMCA).
- Mental Capacity Act (MCA) 2005 training was completed as part of mandatory training. All staff apart from clinical assistants had completed mandatory training or had evidence recorded of training in MCA. At the time of inspection 16% of clinical assistants had completed mandatory training including MCA, with a projected 100% compliance by November 2018. Staff we spoke with demonstrated an understanding of mental capacity and what actions to take if they had concerns about a patient's capacity.
- All staff were aware of the principles of Gillick competency. Any patient under 18 years of age who attended for an ultrasound scan would have a detailed conversation with the sonographer first to ensure they fully understood the process and potential findings from a scan. If the sonographer was content with the patients understanding and ability to consent, patients were asked to sign a specific 16 to 18-year olds consent form.

Are diagnostic imaging and endoscopy services caring?

Good

We previously did not have the authority to rate this service. However, on this inspection we did have authority to rate and we rated it as **good.**

Compassionate care

- During our inspection, we observed the care and treatment of 26 patients and engaged with them during their time at the clinic. All feedback about the service was positive with comments including "they were a very caring team", "they made the experience really lovely for us", "very nice and friendly" and "would 100% recommend".
- The service gathered patient feedback on a regular basis. The service had recently arranged for patients to provide feedback through an online service. All feedback was published on the providers website, as well as a rating system used. For responses which rated the service as three stars or below, staff responded to the comments from the patient and invited them to engage directly with the service to try and resolve any complaints.
- In August 2017, the service gathered feedback from 3,074 patients, of these patients 83% said they were likely to recommend the service. Of those who answered negatively, only 88 patients offered additional reasons as to why they would not recommend the service. The main themes of the responses were disappointed with the services provided (44 patients) and the concerns around staff attitude (22 patients). The remaining reasons were a mixture of disappointment over waiting times, clinical advice and processes and the equipment and environment.
- Patients who attended a location as part of the AQP-NOUS (any qualified professional non-obstetric ultrasound scans) service provided feedback to the contracting service. Any relevant points of feedback for

Ultrasound Direct would be shared by the external stakeholder. We reviewed six anonymised feedback forms which all contained positive comments including 'excellent service' and 'lovely sonographer'.

- We observed most staff treating patients with privacy, dignity and respect during their procedures. In most locations, staff locked the doors to the ultrasound scanning room to prevent anybody entering unnecessarily. We also observed staff drawing curtains or leaving the room whilst patients removed items of clothing for a procedure. Prior to re-entering the room or going into the curtained area, staff asked if the patient was ready for them to come back. However, we did observe one episode of care where privacy curtains were not used and there was no do not disturb sign on the door, which could have resulted in the procedure being interrupted and the patient's right to privacy not being respected.
- Staff made a concerted effort to ensure confidentiality was maintained at all times. We observed clinical assistants lowering their voices when talking to patients on the telephone and staff undertaking the procedures ensured they kept their voices to a level which could not be heard outside of the ultrasound scanning room. We also observed staff checking with patients who had a gender reveal scan whether they wanted a gender specific coloured bag to take souvenirs away in or whether they preferred a gender-neutral colour. Staff recognised even if patients were finding out this information, they did not necessarily want to share the news with others so would always respect the confidentiality of the patient and their wishes.
- Staff saw a range of patients, some of who had a history with the service and some who were attending for a first appointment. We observed staff treating all patients compassionately and empathetically, and would not rush patients who were nervous or upset prior to or during the procedure. The care staff provided was patient centred and patients clearly appreciated this.
- Clinical assistants would be used as chaperones if the sonographer required a chaperone or if the patient requested one. Chaperones were mainly used for ultrasound scans on patients under the age of 18 and for patients undergoing an intimate ultrasound procedure, for example a transvaginal ultrasound scan. Although clinical assistants provided this role, they had not received any additional chaperone training.
- We observed staff introducing themselves to patients and explaining their role during our inspection. This was in line with the recommendations in the National Institute for Health and Care Excellence (NICE) quality standards for patient experiences in healthcare.

Emotional support

- Staff understood the impact the ultrasound scans patients attended the service for could have on their wellbeing, especially if concerning or unexpected findings were discovered during the scan. Staff attended additional training in counselling patients in antenatal screening and breaking bad news to patients to enable them to provide the best emotional support and compassionate care for patients who used the service.
- Information provided by the service before the inspection showed there were some occasions when patients felt staff were insensitive in their comments and did not provide the compassionate care and emotional support required, especially in difficult circumstances when patients attended for difficult reasons. In the patient survey completed in August 2017, there were three patients who commented on having to wait in the same areas after receiving bad news as patients who were having positive experiences.
- However, during our inspection we did not observe any incidents of staff demonstrating anything other than kind, thoughtful, supportive and empathetic care. We observed staff providing emotional support to patients who had a concerning history or patients who had concerns about their pregnancy. Patients also commented on how supportive they were and had 'got their worries out of the way so they could enjoy the experience'.
- Senior staff were aware there were difficulties in some locations when unexpected findings were discovered, and this had been evident in some patient feedback received during the patient survey in August 2017. In all circumstances when patients received some concerning news, staff took the time to comfort the

patient and provide whatever support they required at the time. Once the patient was ready to leave the location, staff escorted the patient to their car, ensuring they were ok to leave the locations.

- If staff recognised patients required additional support, they signposted them to organisations and charities which would be able to do this. One example which staff gave was the Miscarriage Association. This was a common organisation that they signposted patients to.
- At the end of all procedures, patients were always given advice of what to do if they had concerns around their health and wellbeing. We saw pregnant patients being advised to contact their midwives if they had concerns following their appointment. For patients who attended for non-pregnancy related scans, staff advised them to contact their GP if they had concerns following the scan.

Understanding and involvement of patients and those close to them

- We saw staff taking the time with patients to explain the details of the ultrasound scan they had chosen and to ensure they felt part of the experience and comfortable asking questions. Patients told us they felt very comfortable during their procedure and felt able to ask staff questions. One patient told us "they didn't feel rushed and staff answered all their questions".
- During the ultrasound scans, staff constantly talked with the patient and described what it was they were seeing. On one pregnancy related scan, the staff member asked the patient if they had any name for the baby, when the patient responded, the staff member referred to the baby by the chosen name to ensure the appointment was personalised for them.
- Relatives or friends who accompanied the patient were also encouraged to ask questions about the ultrasound scan if they needed something clarifying. Although we did not observe any relatives asking questions, one relative did tell us they appreciated being involved with the appointment and the staff had made the experience really special for them.
- At the end of the scan, staff went over again any information they found, this was then followed up with staff providing the patient with a copy of the report they had completed. This provided patients and their relatives with another opportunity to ask any questions about the procedure they had just experienced before departing.
- The service had a relaxed policy towards patients bringing their children with them. We observed staff engaging with and involving the children during ultrasound scans. Staff used phrases which were appropriate for children to understand and ensured they felt part of the whole appointment. During pregnancy related scans, we even saw staff providing the children with their own picture of their new sibling. Patients told us how they appreciated this extra touch and how delighted they were to share the experience with the whole family.
- Staff were also able to adapt the language and terminology they used when discussing the procedure with the patient themselves. The service provided ultrasound scans to a range of patients and was therefore important for staff to ensure they always made sure they used appropriate language which the patient understood.
- Discussions around terms and conditions and pay were completed sensitively before the ultrasound scan took place. This also enabled staff to check what patients understood about the scan they had booked in for and their reasons for requesting the scan.

Are diagnostic imaging and endoscopy services responsive to people's needs? (for example, to feedback?)

Good

We previously did not have the authority to rate this service. However, on this inspection we did have authority to rate and we rated it as **good**.

Service delivery to meet the needs of local people

- The service had a sub-contract to a provide AQP NOUS (any qualified professional non-obstetric ultrasound scans) service. These services were provided at two GP

clinics which meant services were provided to local people in a local setting, rather than them having to travel considerable distant to a local acute hospital for an ultrasound scan.

- Clinic locations were appropriate to meet the needs of the patients who attended for ultrasound scans. Satellite clinics which were provided in retail location all had the same floor plans to ensure consistency in the provision of services.
- All clinics we visited were child friendly and welcomed families to bring children of all ages along to appointments. We found all clinics had a selection of wipeable toys which children could play with.
- There was free car parking at clinic locations which patients could use. There was clear signage for patients to follow to clinic locations.
- The service offered a range of appointment times and days to meet the needs of the patients who used the service. Senior staff told us there was a large demand for appointment times that were later in the day and at weekends, they had therefore organised the regional clinic structure to ensure appointments covered this demand across the regions it operated in. Appointment times for private ultrasound scans were available from 8am until 9pm, Monday to Sunday, although this would be spread across a region and may not necessarily be provided at just one location.
- Scanning appointment for AQP-NOUS ultrasound scans were provided two days per week. These were not set days, but covered the working week (Monday to Friday). Appointment times ranged between 8am until 5pm.
- Appointments for private ultrasound scans were booked using the providers website or patients could ring the administration team who would book them into a location which best suited their requirements. Appointments for the AQP-NOUS ultrasound scans were booked through the main contractors of the service.

Meeting people's individual needs

- Staff were aware of the individual needs of patients living with dementia and those with a learning disability, however they rarely had patients attend their clinics for an ultrasound who had complex needs. Staff told us the only times they had encountered patients with complex needs was during the AQP-NOUS service. During these scans, they would ensure the patients' needs were met and carers or relatives could stay with them. Appointment times would also be extended to ensure patients were not rushed causing the patient less distress.
- Staff had access to a translation and interpretation service for patients whose first language was not English. Staff we spoke with knew how to access this, although none had needed to use it.
- All clinical locations we visited had minimal patient information literature available for patients to take away with them. The leaflets which were available for patients were only available in English, and were only available in standard print. Staff told us if leaflets were required in a different language or larger print, they could request these or directed patients to review the information electronically.
- Senior staff told us they had ensured all satellite locations could meet the needs of bariatric patients. All coaches used for ultrasounds were able to take the weight of patients who weighed over 28 stones. For patients who were seen as part of the AQP-NOUS, if patients had a body mass index (BMI) of over 35, additional patient information was required before their ultrasound scan to ensure their needs were met.
- Most satellite clinics were accessible to patients with a disability as most clinics were on one level. For satellite clinics which were not on one level, staff ensured this information was relayed to patients either during the appointment booking or during a follow up confirmation email.

Access and flow

- Waiting times for the AQP-NOUS ultrasound scans were between two to three weeks, this was well below the six weeks standard wait within the local acute hospitals. Information provided about this service showed staff from the service were willing to be flexible where possible with clinic appointments, especially if the referring practitioner deemed the patient as 'urgent'. We observed a patient being referred under an urgent request who was given an appointment within a week of their referral.

- There were no waiting times for the ultrasound scans performed for private patients. Most patients arranged an appointment within a day or two of contacting the service, or a within a timeframe which suited them. However, there was also the opportunity to book appointments for the same day.
- Information provided before the inspection showed there had been a number of complaints raised about the length of time patients waited on the day of their ultrasound scan. Staff told us delays could occur with some pregnancy related ultrasound scans due to the position of the baby. In these circumstances, staff tried to keep waiting times to a minimum by asking patients to return later. If there were delays, staff would keep patients up-to-date with times and would offer complimentary refreshments.
- There was a process in place to monitor DNA (did not attend) appointments, although staff told us for the private ultrasound scans, there was not really a problem. If patients intended not to attend for their appointments they would contact the service and arrangements would be made to either change the appointment or offer a refund of the deposit (reason for cancellation and length of notice dependant).
- It was a requirement under the sub-contract to monitor the patients who DNA for AQP-NOUS ultrasound scans. Information was shared with the contractors each month on patients who had DNA their appointment. Information provided showed between August 2017 to July 2018, the average DNA rate per month was 5.9% (ranging between 2.11% and 10.45%). Information about patients who DNA their appointment was fed back to the referring practitioner.
- Patients who attended for a private ultrasound scan were given a copy of any significant measurements taken during the procedure. If an additional report was required due to unexpected findings, this would be completed and sent to a healthcare practitioner within 24 hours.
- Patients who attended for an ultrasound scan on the AQP-NOUS contract had a report completed at the time of their appointment which was uploaded on to the electronic system and shared immediately with the referring practitioner.

Learning from complaints and concerns

- The service had a complaints policy in place, which was last updated in November 2016. This provided staff with the details of action to take if a complaint was made either by telephone or email. The policy recorded the highest level of escalation of complaints was to head office level, there were no details recorded on what happened if complainants were still not satisfied with the outcome of the complaint once investigated and responded to by head office. Senior staff told us they would direct patients who were still dissatisfied with the outcome to the CQC. At the time of our inspection, this had not occurred with any complaint raised.
- The service recorded 117 complaints between July 2017 and June 2018, eight of these were upheld by the service. Staff told us not all complaints had been formally raised by the patient with the service, a large proportion of these complaints were from the electronic feedback service which had recently been instigated.
- All complaints and negative feedback on the electronic feedback service were treated with the same level of importance. There was an operational manager who had oversight of the complaints which came through and ensured the complaints process was followed through correctly and completely.
- Complaints were investigated by the regional managers. All complaints were responded to within seven working days. Regional managers would respond to patients usually by telephone or by email, preferably the patients preferred method of contact. There was usually not a requirement for any face-to-face meetings to be held.
- The most common reason for patient complaint was around the ultrasound scan image, especially for patients who attended for a 4D (four dimensional) scan. This was due to positioning of the baby and the gestation stage of the mother which could impact on the scan image. All staff we observed explained at the beginning of ultrasound scans this potential difficulty to manage patient expectations. If there were

difficulties, staff attempted to deal with the situation in a professional manner, whether that was through offering another attempt later in the day or offering the patient a free return on a different day.

- Staff constantly asked patients if they were happy with the service and the ultrasound scan they had received. If any patient had told them of their dissatisfaction, staff told us they would provide details of how they could complain. Not all locations had visible complaints information on display, however the website had a section which advised patients on the complaints process if unhappy with the service.

Are diagnostic imaging and endoscopy services well-led?

Good

We previously did not have the authority to rate this service. However, on this inspection we did have authority to rate and we rated it as **good.**

Leadership

- All staff spoke overwhelmingly positive about the leaders of the service, from their direct line managers to the directors of the company. All leaders were fairly visible, knowledgeable and approachable. As the service was far reaching, in areas that were more remote, staff told us leaders were always accessible even if not visible.
- All leaders maintained their skills and knowledge through continuing with clinical practice. This demonstrated to staff their clinical currency and demonstrated positive role modelling.
- All staff told us leaders were keen to keep developing the service to ensure the patients received a quality service. There had already been many changes to the service which had the patient at the heart of all developments and changes made.
- Staff felt the leaders had a genuine interest in developing staff's abilities and skills through the implementation of the Ultrasound School. The training and continuing professional development opportunities that this provided staff was considered as exemplary and something which they had not experienced anywhere else.
- Many of the regional managers had worked for the service for many years and had started off as sessional sonographers. The senior members of the service had provided them with the opportunities to develop their leadership skills and gain promotion within the service.

Vision and strategy

- The service had a clear vision to offer a values based service to meet the needs of the patients (customers). The service aimed to continue to grow and offer a comprehensive quality assured private ultrasound scanning service to a wider range of patients (customers).
- The most recent staff survey from 2017 identified clinical staff (sonographers and scan buddies) were not as certain about a vision and strategy for the service, than staff from the 'headquarters' and regional management staff groups. However, during our inspection, we found staff were more aware of the vision of the service and felt they were part of the vision and future of the service.
- Senior staff told us the strategy for the future was to concentrate on succession planning and growing the company through looking at additional ultrasound services. The AQP-NOUS sub-contract had been successful for the company and senior staff recognised this as an area full of potential for the service. The service had also undergone a partnership with an external provider who concentrated in fertility services, this had also been factored into the continued succession of the service.
- Senior staff (the directors, head office managers and regional managers) met on a bi-annual basis where the vision and strategy of the service was reviewed and progression against the current vision and strategy discussed. Minutes from the most recent managers meeting demonstrated the vision and strategy of the service was a regular agenda item. The minutes from the June 2018 meeting identified a new three-year plan was currently in progress and would be available to all staff imminently.

Good

Diagnostic Imaging and Endoscopy Services

Culture

- All staff we spoke with told us they felt respected and valued by their managers and fellow colleagues. Staff told us working for the service had a very 'family feel' to the service as many had started to work for the service in the earlier days. If they had any concerns, staff felt they were able to approach anybody for help and advice, even if they were not at work at the time.
- Staff we spoke with told us they felt proud to work for the service and they enjoyed the work they did within the clinics. This was supported by information provided prior to the inspection from the staff survey 2017. In this survey, 96% of staff would recommend the service as a place to work and 97% of staff would be happy to recommend to a family or friend to receive care and treatment.
- Staff had presented the directors of the service with a 20-year anniversary gift earlier this year in recognition for their hard work and dedication to the service. Senior staff told us this demonstrated the overwhelmingly positive culture and was a reflection of the 'happy family' of staff they had working for the service.
- Staff told us they were regularly updated with important information about the service which supported a positive culture. Many teams had developed their own secure social media groups as a way of keeping in contact in between the shifts they completed for the service.
- Regulation 20 of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014 is a regulation, which was introduced in November 2014. This regulation requires the organisation to be open and transparent with a patient when things go wrong in relation to their care and the patient suffers harm or could suffer harm, which falls into defined thresholds. The duty of candour regulation only applies to incidents where severe or moderate harm to a patient has occurred.
- The service had an open and honest culture. Any incidents or complaints raised would have an open and honest 'no blame' approach to the investigation, however in circumstances where errors had been made, apologies would always be offered to the patients and staff would ensure steps were taken to rectify any errors. Staff were aware of the duty of candour regulation; however, they had not had any incidents which met the criteria where formal duty of candour had been required to be implemented.
- The open and honest culture also extended to all staff members. Staff told us they would feel comfortable in raising any concerns they had with any of the managers, as all were seemed as approachable. They felt confident in their abilities to take their concerns further without fear of reprisal.
- There was a process in place to manage staff who poorly performed of whose behaviour was inconsistent with the expected values and standards of the service. Information in the staff survey 2017 showed a number of staff who had raised concerns about the way in which they had been treated (harassment, bullying or abuse), however during our inspection, staff did not identify this as an issue and only spoke positively in how they were treated by staff of all levels.

Governance

- There was a corporate level clinical governance board who met monthly and were responsible for overseeing all elements of clinical governance. Each region had a clinical governance lead who provided a report to the board with any specific governance issues from their area. An update from the meeting was then produced and cascaded to all regional managers. Staff we spoke with told us they received an update on the clinical governance meetings from their managers, usually through email.
- The directors and national managers had a monthly meeting to discuss the future of the service and any issues impacting on the business continuity. Important issues and risks from the clinical governance meetings which required escalating would also be discussed during these meetings. Feedback and minutes from these meetings was cascaded down to regional teams.
- The service had a full team of head office managers working from their registered location. This team ensured all service level agreements and contracts were monitored and managed appropriately to ensure a smooth service was provided.

- At the time of our inspection, the human resources (HR) systems were being updated to a more streamlined and intuitive process which will enable managers to see at a glance when staff were required to update important documents or training. We reviewed 12 random staff files (including all roles and levels of responsibility). We found in all files staff had not undergone an occupational health check to ensure all required vaccinations were up-to-date and the staff member had no additional health requirements. The Department of Health Green Book and the Health and Social Care Act (2008) Code of Practice on the Prevention and Control of Infections and Related Guidance advised that employers should seek satisfactory evidence of protection, which includes either confirmation of vaccinations given or results of positive antibody tests. Staff spoke confidently about the clinical staff having Hepatitis B vaccination evidence, however they had not considered the other diseases which healthcare workers should have evidence of immunity for, including Varicella Zoster and Rubella, both of which were harmful to the large proportion of patients who used the service. Since our inspection, the senior management team provided information on how they planned to address this going forward along with an example of the questionnaire staff would be given regarding their immunisation history.
- We also found two out of 12 staff files had no evidence of references and three out of 12 staff files had no record of a disclosure and baring service (DBS) check having been completed. Staff told us one member of staff with no references on file had worked for the service almost for as long as the service had been operating and therefore could explain why no references could be found. Staff also told us the planned HR system change over may also have impacted on the files provided.
- Staff told us clinicians who worked as part of the sub-contract were required to apply for a new DBS certificate on a three-year cycle, and we saw evidence of staff who had recently had to renew their DBS certificate. However, for the rest of the staff who worked for the service, there was no policy in place which required them to renew their DBS. The department responsible for DBS checks had not specified a validity time frame for DBS certificates, however it is a requirement of employers to risk assess their work force, the work they complete and risk of potential abuse and formulate their own policy on this. Since our inspection, we received information which demonstrated that the service had updated their own DBS policy and would complete renewals on a five-yearly basis for all staff.
- The provider did not require individual practitioners to hold their own indemnity insurance, all staff working for the service were covered under the providers indemnity insurance. We saw copies of the insurance certificate displayed in all clinical areas.

Managing risks, issues and performance

- At the time of our inspection the service did not hold a risk register. However, risk assessments were completed for any risks identified and oversight and risk managing of these was through the clinical governance meetings and if escalation was required, through the managers meeting. Senior staff told us this had been an appropriate was of managing risk, however since starting the CQC inspection process, they had reconsidered their approach to risk management and were looking at ways to improve this. During our inspection, we found no additional risks which the senior staff (management) were not aware of.
- Risk assessments were completed on a standard template to ensure consistent information was used. All templates had the risk identified, mitigating/ control measures and residual risk following control measures. There was also review dates on all risks. We saw examples of clinic risk assessments and office risk assessments, all had been completed with adequate information, and updated with any additional measures taken to reduce the risk.
- At the time of inspection, the service had just initiated an annual audit programme with regular meetings to monitor the programme and ensure learning from outcomes is disseminated. Prior to the implementation of this, the service had completed regular audits of the quality of ultrasound scans and reports, and full audit reports and action plans completed to ensure performance was improved. On the most recent audit, the results demonstrated staff

were performing ultrasound scans and completing reports to a high level. The service had also completed re-scan audits and tried to implement target training and learning as a result of the findings.

- There was a key performance indicator (KPI) for the number of ultrasound scans to be performed per hour. This KPI was managed by regional managers and monitored through both the clinical governance meetings and managers meeting.
- In all locations where clinical services were provided, the service did not own the buildings and therefore in the event of a power shortage, would follow the recommendations of the staff who owned the building. Backup generators were therefore not tested by the service, however staff told us there would be no impact to patients other than requiring a re-scan at the next available opportunity in the event of a power cut.
- The service followed the direction of the staff who owned the buildings for risks including fire. The service was responsible for maintaining the equipment in the areas they operated and were responsible for the patients and visitors who attended the clinics. During our inspection, we were requested by staff to sign visitor logs and observe the fire procedures for specified areas.
- All clinical areas had a resource folder which contained the most current versions of policies and procedures as well as other useful information and contact details (for example, local safeguarding contact details). In addition to this, sonographers had the ability to access policies and procedures on an electronic system.

Managing information

- Terms and conditions for the service were available for patients to review on the website as well as being provided a laminated copy to read when they attended for their appointment. When patients had booked their ultrasound scan, a copy of the terms and conditions were also emailed to them. A deposit was taken from the patient at the booking stage and the rest of the payment was taken before the ultrasound scan prior to the scan taking place. Clinical assistants would discuss the ultrasound scan with them and pertinent points including what the scan would include when acquiring the remainder of the payment from the patient.
- The service completed advertisement in accordance with advertising legislation. The senior staff had decided to restrict the advertising of the service to ensure targeted approaches were made. They had decided against using promotional groups to market the services provided due to this not being compatible with the services values and standards. Staff told us a large proportion of patients using the service was through previous use of the service or word of mouth.
- The service was aware of the requirements of managing a patient's personal information in accordance with relevant legislation and regulations. Staff told us when the General Data Protection Regulations (GDPR) were released, they were reviewed to ensure they were operating within the regulations. Staff told us they viewed breaches of patient personal information as a serious incident and would therefore manage this as a serious incident and would escalate to the appropriate bodies.
- The service used many IT systems which were all role specific at the moment, however investing in improving the IT systems available to make them more intuitive and user friendly was a main objective and there was a manager employed to specifically manage this and work with external providers to bring this to fruition. This staff member was also integral to the day-to-day management of information and ensuring staff were equipped to work with these systems and upload important documents post procedures.

Engagement

- The service had engaged with an external company to develop a patient feedback service. All patients who used the service had an email sent to them requesting feedback and asked them to rate the service. This information was then pulled through to the services website where feedback was available to all future patients. Staff reviewed the feedback they received and responded to patients who rated them as three

stars or below. Staff told us this had improved their overview of the services being provided across all locations and had helped to improve services where needed.

- The service also completed their own internal patient feedback survey on an annual basis which was based on the friends and family test performed in the NHS. The service last run this survey in August 2017 and it showed most patients (83%) were very likely to recommend the service to their family and friends. For those patients who would not recommend it or less likely to recommend the service, they were given the opportunity to provide additional comments on why this was the case.
- The service considered both approaches to patient feedback as a serious way of learning from patients and trying to improve the service. Staff told us additional training in customer service had been provided for staff as a result of patient feedback as well as updating procedures to ensure staff communicated clearly with patients what was involved in the ultrasound scan they had booked in for. On reflection of the feedback received, staff told us the majority of feedback centred on patient expectations of the service they expected to receive in compared to what they received, so all the learning had been targeted at managing patient expectations.
- The service had implemented an annual staff survey. The survey was last completed in November 2017 and there was a 48% response rate. The survey echoed the types of survey completed in the NHS. The majority of information gained from the survey demonstrated staff were happy with the service and the work they completed at the service. However, the survey had highlighted some concerns around satisfaction with the job and communication received as well as some issues with harassment and bullying. The service had worked hard to try and overcome these issues, an example of where work had been completed was around communication within the teams. At the time of our inspection, all staff were complementary about the service is all aspects and no complaints were raised is relation to any areas reported in the staff survey.
- Staff had created regional social media groups to engage with other members of the team. Within these groups, staff promoted specific related topics (mainly pregnancy related) and updated information for others to be aware of. Staff also had a private messaging service which enabled them to communicate in a private manner.
- Staff told us they tried to engage with other members of the Ultrasound Direct team from across all locations. Regional managers were able to do this at the bi-annual meetings they attended, other staff members had the opportunity to engage with others either at training events or the annual Christmas party.
- The provider had a process in place to recognise staff who had 'gone above and beyond' through a monthly awards process. We also saw examples of regional managers acknowledging their staff through an 'employee of the month' award.
- Staff had formulated a positive relationship with external stakeholders and partners. Feedback from external stakeholders showed they had regular engagement with the managers of the service as well as frequent engagement with the sonographers who completed the clinics. The feedback was extremely positive and described the relationship as open and transparent which enabled them to provide a service to meet the requirements of patients needing the service.

Learning, continuous improvement and innovation

- Staff told us the introduction of the Ultrasound School had been an improvement made to the service which provided all staff the opportunity to develop their skills and in some circumstances, learn new skills. Some staff told us they saw this as innovative practice as there were no other services or organisations which provided this service for their staff. Staff who had used this to enhance their clinical skills were extremely complimentary about this and saw it as a valuable asset.
- Staff told us the managers (directors) of the service were always looking for ways to improve the service to provide a more enhanced service for the patients who choose to use them. An area where work was underway to improve the service was regarding the management of ultrasound images and the recording of images which will improve the already streamline process of reporting ultrasound scan findings.

- The senior staff told us they were a service who thrived on learning from situations, the most recent situation they were learning from was the CQC inspection process. The provider information request (PIR) which was sent in preparation for the inspection had enabled them to review some of their current processes and identify ways in which they could improve. This will not only benefit them as a service, but ultimately be an improvement on the service provided to the patients.

Outstanding practice and areas for improvement

Outstanding practice

- The Ultrasound School and all-round investment in staff training was viewed by all staff as innovative and impressive. The technology used within the school and the training provided was not provided in any other services and staff felt very fortunate to be able to benefit from this.
- The provider ensured staff who were not on a professional register (HCPC or NMC) were registered with the Society of Radiographers. This demonstrated the provider was aware of the professional accountability and requirement for a transparent workforce. This also demonstrated the sonographers who worked for the service were suitably qualified to undertake the role of sonographer.

Areas for improvement

Action the provider SHOULD take to improve

- The provider should ensure all clinical assistants complete the mandatory training topics as part of the planned programmed of training within the timeframe specified.
- The provider should ensure the current planned installation of portable handwashing sinks is completed to encourage the good principles of infection prevention and control, and reduce the risk of transmission of infection to patients.
- The provider should ensure all policies and procedures contain the most current legislation and standards and the most up to date evidence based information.
- The provider should consider providing all staff with training on additional safeguarding concerns, such as child sexual exploitation.
- The provider should consider how they provide assurance that all staff have evidenced undergoing an effective vaccination programme for healthcare staff.
- The provider should consider the on-going risk of having carpeted flooring in some clinical locations and the risk this presents to patients.
- The provider should consider how they support their staff to take on the role of a chaperone when required.
- The provider should continue to implement the audit programme so that patient outcomes can be evidenced and areas of improvement identified and worked on.