East Anglia Ultrasound Services

Quality Report

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

Ratings

Overall rating for this location	Requires improvement
Are services safe?	Requires improvement
Are services effective?	
Are services caring?	Good
Are services responsive?	Good
Are services well-led?	Requires improvement

Summary of findings

Letter from the Chief Inspector of Hospitals

East Anglia Ultrasound Services is operated by East Anglia Ultrasound Service Ltd and provides diagnostic routine ultrasound imaging services for private patients at its location in Dry Drayton, Cambridgeshire. The provider takes blood samples for prenatal testing, that are processed at laboratories in London. The service has operated since 2014 and relocated to its present location in January 2018. The provider offers paediatric scans and early foetal scans to patients from a wide catchment area including London, Nottingham, Norfolk, Ipswich and the surrounding areas.

We inspected this service using our comprehensive inspection methodology. We carried out a short notice announced inspection on 19 December 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.

Services we rate

We rated it as requires improvement overall.

We found areas of practice that the service needed to improve:

- The providers safeguarding adult policy did not reflect up to date guidance in relation to safeguarding adults.
- The provider did not have a policy in place to safeguard children.
- The provider had no overarching governance process or risk management system to improve performance.
- Some policies and procedures were out of date, not version controlled and did not contain up to date guidance.
- The providers statement of purpose did not reflect its services for patients under 18 years of age.
- The provider did not submit statutory notifications CQC in line with incident reporting guidance, and its incident policy was not sufficient to guide staff on incident reporting processes.

We found the following areas of good practice:

- The environment was visibly clean and the providers location was fit for its purpose to meet the needs of the patients it served.
- Patient feedback was universally positive, patients felt engaged in their care and respected by the staff.
- The provider took complaints seriously and complaints were dealt with in line with local policy.
- The provider had improved record keeping processes and introduced an information technology (IT) based record management system to reduce the risk of information governance breaches.

Following this inspection, we told the provider that it must take some actions to comply with the regulations to help the service improve. We also issued the provider with one requirement notice that affected diagnostic imaging. Details are at the end of the report.

Amanda Stanford

Deputy Chief Inspector of Hospitals (Central)

Summary of findings

Overall summary

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 service as requires improvement for safe and well led. We rated caring and responsive as good. Effective was not rated. Systems for the management and referral of safeguarding concerns did not reflect current best practice. There was no safeguarding children policy in place. The service did not always manage patient safety incidents well, staff recognised incidents but did not report them appropriately. Policies, procedures and guidelines did not always reference current legislation, evidence-based care and treatment or best practice.

However, we also found the service provided mandatory training in key skills to all staff and made sure everyone completed it. The service controlled infection risk well. The service had enough staff to provide the right care and treatment. Staff cared for patients with compassion. Feedback from patients confirmed that staff treated them well and with kindness. The service made sure staff were competent for their roles. Managers promoted a positive culture that supported and valued staff. The service engaged well with patients, staff, and the public.

Summary of findings

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Requires improvement

Location name here

Services we looked at
Diagnostic imaging

Summary of this inspection

Background to East Anglia Ultrasound Services

East Anglia Ultrasound Services is operated by East Anglia Ultrasound Service Ltd. The service provides routine scans for obstetrics, gynaecology, abdominal and specialised scans such as muscular skeletal (MSK), testes, hernias, breasts, lumps, deep vein thrombosis (DVT), carotid arteries, paediatric scans and four dimensional (4D) scans.

The service is registered for diagnostic and screening procedures, during our inspection the provider informed us they were also providing scans for children under 18 years of age, this was not recorded on their statement of purpose.

The service has a registered manager in post since registering with the CQC. At the time of our inspection the nominated individual was leading the service while the registered manager was on an extended period of leave. The provider had not informed CQC of this and we advised them to send the appropriate notification to us, which they did following our inspection.

Our inspection team

The team comprised a CQC lead inspector who had completed the single speciality diagnostic imaging training and one other inspector. The inspection team was overseen by Fiona Allinson, Head of Hospitals Inspection....

How we carried out this inspection

The registered location was registered to provide:

- Diagnostic and screening procedures.

During the inspection, we visited the registered location in Cambridgeshire. We spoke with three staff including the nominated individual (sonographer) and receptionist. We spoke with five patients and their relatives and reviewed five 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.

Information about East Anglia Ultrasound Services

This was the first inspection of the service since the most recent update to the registration in January 2018. The service has not previously been inspected.

Activity (April 2018 to December 2018)

- The service performed ultrasound scans on 779 adults, five ultrasound scans on children and two pregnancy related scans on patients under 18 years of age.
- All activity within the service was privately funded.

Summary of this inspection

- Early pregnancy related scans accounted for 35% of activity, non-invasive prenatal testing 8%, growth scans 7%, 4D scans 7%, and pelvic scanning (Follicular) 7%. The remainder of scans were in relation to muscular skeletal (MSK) 1.5%, gender 5%, dating scan 2%, anomaly 2%, second trimester reassurance 4%, abdominal 5%, endometria thickness 2.4%, breasts 3%, and bloods 2%.

The nominated individual and reception staff worked full time at the service, and the provider employed two sonographers, from other health care environments, on a sessional basis. The registered manager was also a sonographer, and worked part time at the service. The service did not use any medicines and therefore they did not have an accountable officer for controlled drugs (CDs).

Track record on safety between 4 October 2017 and 4 October 2018:

- There were no never events.
- There were two serious incidents, one low harm and one medium harm.
- There had been one complaint, which was upheld and 110 compliments.

Services accredited by a national body:

- The service had no accreditations by national bodies.

Services provided under service level agreement:

- The service had no service level agreements with other providers.

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?

Are services safe?

Requires improvement 

We rated safe as requires improvement because:

- The service did not always manage patient safety incidents well, staff recognised incidents but did not report them appropriately.
- The provider did not have an up to date policy for safeguarding children.
- At the time of our inspection, the provider had no access to staff trained at level three safeguarding children. However, the nominated individual completed this immediately following our inspection.

However, we also found:

- Staff we spoke with understood how to protect patients from abuse, however systems for the management and referral of safeguarding concerns did not reflect current best practice in relation to safeguarding adults and the provider had no safeguarding children policy in place.
- The service provided mandatory training in key skills to all staff and made sure everyone completed it.
- The service controlled infection risk well. Staff kept themselves, equipment and the premises clean. They used control measures to prevent the spread of infection.
- The service had suitable premises and equipment and looked after them well.
- Staff completed and updated medical questionnaires for each patient. They kept clear records and asked for support when necessary.
- The service had enough staff to provide the right care and treatment.

Are services effective?

We do not rate effective.

We found:

- The service made sure staff were competent for their roles. Managers appraised staff's work performance and provided support and monitored the effectiveness of the service.
- Staff of different kinds worked together as a team to benefit patients.

Summary of this inspection

- Staff were aware of the importance for gaining consent from patients before conducting any procedures. We observed staff gaining consent from patients prior to starting their ultrasound scan.

However, we also found:

- When we reviewed policies, procedures and guidelines produced for the service to implement locally. We found few of these referenced to any current legislation, evidence-based care and treatment or best practice.

Are services caring?

Good

We rated caring as good because:

- Staff cared for patients with compassion. Feedback from patients confirmed that staff treated them well and with kindness.
- Staff provided emotional support to patients to minimise their distress.
- Staff involved patients and those close to them in decisions about their care and treatment.

Are services responsive?

Good

We rated responsive as good because:

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

Are services well-led?

Requires improvement

We rated well-led as requires improvement because:

- The nominated individual was leading the service while the registered manager was on an extended period of leave.
- The service did not systematically improve service quality and there was a lack of overarching governance.
- The provider did not report specific incidents in line with CQC guidance.
- The providers statement of purpose did not reflect its services for patients under 18 years of age.

However,

Summary of this inspection

- The manager promoted a positive culture that supported and valued staff, creating a sense of common purpose based on shared values.
- The service engaged well with patients, staff, and the public.
- The service had a vision for what it wanted to achieve however there were no long-term plans to develop the business any further.

Detailed findings from this inspection

Overview of ratings

Our ratings for this location are:

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

Requires improvement

Diagnostic imaging

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

Are diagnostic imaging services safe?

Requires improvement

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 **requires improvement.**

Mandatory training

- **The service provided mandatory training in key skills to all staff and made sure everyone completed it.**
- At the time of our inspection we reviewed all staff personnel files and noted all staff had completed their mandatory training through face to face and on-line E-learning via an external training provider.
- Training included 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 provider did not have a policy for mandatory training, all training records were kept securely inside a locked office.
- The provider used appraisal to discuss when mandatory training was required and offer additional training courses to increase staff knowledge and skills.
- The providers statement of purpose did not specifically relate to the staff training provided in order to meet the needs of patients under the age of 18 years.. We did not see any additional training to support this activity, however as most staff were sessional, staff we spoke with told us this area of practice was covered by their substantive employer.

Safeguarding

- **Staff we spoke with understood how to protect patients from abuse, however systems for the management and referral of safeguarding concerns did not reflect current best practice in relation to safeguarding adults and the provider had no safeguarding children policy in place.**
- The providers adult safeguarding policy was dated January 2018 and due for review in January 2020. The policy did not relate to key areas in relation to the safeguarding of adults, including female genital mutilation (FGM), forced marriage, domestic violence, modern slavery or on-line protection.
- All staff had completed level two adult and children safeguarding courses within the last 12 months.
- At the time of our inspection, the nominated individual told us that none of the staff had completed a level three safeguarding children qualification and the provider had no links to external advice or guidance in relation to safeguarding children. Following our inspection on the 19 December 2018, the provider submitted certification showing they had completed a designated safeguarding officer (level 3) children's course on the 20 December 2018. This demonstrated responsiveness to our inspection findings and that the provider had taken our concerns seriously.

Requires improvement

Diagnostic imaging

- The service did not have a formal system in place where alerts for known safeguarding concerns could be activated.
- Staff had access to a local NHS trust policy for safeguarding adults and used the NHS mini pocket books for additional safeguarding guidance.
- Staff working within the service also worked within other health related environments and received additional safeguarding training within these roles.

Cleanliness, infection control and hygiene

- **The service controlled infection risk well. Staff kept themselves, equipment and the premises clean. They used control measures to prevent the spread of infection.**
- The clinical environment we visited during our inspection was visibly clean and tidy. All areas had evidence of a cleaning schedule which was signed when staff had completed the cleaning duties.
- The clinical area had dedicated hand washing facilities, staff had access to hand sanitizer and disposable wipes for cleaning of surfaces and the treatment couch.
- We observed staff decontaminating the equipment after use. Staff used an appropriate cleaning product which was recommended by the equipment manufacturer for ultrasound probe decontamination and disposable camera covers for probes.
- We observed staff in the clinical environment 'bare below elbow' and staff had access to appropriate personal protective equipment (PPE).
- Patients we spoke with following the treatment told us that staff used gloves and aprons during these procedures and washed their hands. 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 to perform venepuncture (blood taking) for certain pregnancy related blood tests.
- The clinical area used hard flooring, this was visibly clean and in good condition which enabled staff to clean spillages and minimise the spread of any infection.
- 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.
- The provider had an infection prevention and control policy which was in date for review. However, the guidance for staff hand washing did not meet current best practice guidance, for example the World Health Organisations (WHO) five moments for hand hygiene.
- At the time of our inspection, the service had not completed hand hygiene audits.

Environment and equipment

- **The service had suitable premises and equipment and looked after them well.**
- The service was provided from a single storey location with a dedicated reception area, treatment room, toilets and staff kitchen. Patients pressed a door bell to gain access to the environment and were led to the waiting area by reception staff, all staff wore identify badges on a lanyard. The reception area was welcoming, had an area for children to play and reading materials for patients.
- The service did not have resuscitation equipment in its clinical area. The provider did not feel this was necessary given the low acuity of the patients using the service.
- All electrical equipment we inspected had been checked annually as per safety recommendations and appropriately labelled.
- All servicing of the electrical equipment was completed by an external company. Staff relied on the external company to alert them as to when the next service was due.
- Staff told us they had sufficient amounts of equipment to provide the service and the equipment they had was of a decent quality.

- We observed staff segregating clinical and domestic waste correctly, into waste bins which were enclosed and foot operated.
- The management and disposal of sharps and waste was completed in accordance with policy by an external company. We found two sharps containers, one was dated and signed the other was not. The provider remedied this immediately.

Assessing and responding to patient risk

- **Staff completed and updated medical questionnaires for each patient. They kept clear records and asked for support when necessary.**
- The service had no process in place for the management of patients who suddenly became unwell during their procedure. Staff told us in the event of a cardiac arrest, they called 999 for an ambulance. All 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 which they called care pathways, to guide staff on what actions to take if any suspicious findings (whether expected or unexpected) were found on the ultrasound scan performed. Staff gave 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.
- Patients who attended for ultrasound scans in the early stages of pregnancy, who staff subsequently identified concerns with the foetus or identified the patient was having a miscarriage or ectopic pregnancy were advised to attend their general practitioner or local NHS treatment centre for further assessment and follow up.
- The provider did not have an eligibility criterion for the service, however the provider used the medical questionnaire to screen patients and if there were any concerns the provider would refuse treatment and give a full explanation why.
- 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 majority of ultrasound scans they performed. The service used their own check lists during scans to ensure the correct pathways were followed.
- 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 were 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'. The ultrasound scans performed during the routine antenatal journey were usually looking for other specific information in relation to the well-being of the baby.

Staffing

- **The service had enough staff to provide the right care and treatment.**
- This was a privately-owned service that offered ultrasound services to self-funding patients. The nominated individual worked full time and registered manager part time and both were business partners in the service. The provider employed a full-time receptionist and two other sessional
- Staffing was planned based on bookings taken. All clinics had at least one sonographer present and a receptionist to greet patients and complete all the necessary records for treatment.

- Working hours for clinics varied and were responsive to the patient group. We noted early morning, evening and weekend sessions could be booked based on the patient's availability. Staff worked together to agree a rota where a sonographer and receptionist would be available.
- The service did not use locum, bank 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.

Records

- **Staff kept detailed records of patients' care and treatment. Records were clear, up-to-date and easily available to all staff providing care.**
- The service used a combination of paper and electronic records. Paper records were used by reception staff to record initial medical assessment and patient consent. The documents were then scanned by the reception staff onto the providers secure IT system. Reception staff then immediately shredded the medical assessment form and gave the original consent form to the patient for their keeping.
- Sonographers recorded their reports onto the IT system during the ultrasound scan to record essential information (for example, measurements). A copy of this record could be printed for the patient at the end of their procedure for them to take with them or sent to them via a verified email address. The provider checked with the patient that their email address was correct prior to sending any information and would also send a test message to ensure the email address was valid.
- We reviewed five patient records during the inspection which had been transferred to the providers secure IT system. 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 and did not store or administer medications on site

Incidents

- **The service did not always manage patient safety incidents well, staff recognised incidents but did not report them appropriately.**
- Managers investigated incidents and shared lessons learned with the team. When things went wrong, staff apologised and gave patients honest information and suitable support.
- There were no never events reported for the service between 4 October 2017 and 4 October 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.
- The provider used a basic incident report template, for staff to report incidents, however this was not part of a wider incident policy or procedure.
- The provider had two serious incidents reported for the service between 4 October 2017 and 4 October 2018. One incident in November 2017 related to the near miss of an ectopic pregnancy and was rated as medium harm. The other incident in September 2018, related to a breach of confidentiality and rated as low harm. 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.
- We reviewed the two incidents and noted these had been investigated and the provider had followed duty of candour in communication with the patients involved. The provider did not inform CQC of the incidents at the time they occurred. Senior staff were not 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.
- The duty of candour is a regulatory duty that relates to openness and transparency and requires providers of health and social care services to notify patients (or other relevant persons) of certain 'notifiable safety incidents' and provide reasonable support to that person.

Requires improvement

Diagnostic imaging

- Staff we spoke with understood the duty of candour process and the need for being open and honest with patients when errors occur. Senior staff could explain the process they would undertake if they needed to implement they duty of candour following an incident which met the requirements and we reviewed evidence that demonstrated they did this whilst reviewing the providers serious incident reports.

Are diagnostic imaging services effective?

We do not rate effective.

Evidence-based care and treatment

- **We reviewed policies, procedures and guidelines produced for the service to implement locally. We found few of these referenced to any current legislation, evidence-based care and treatment or best practice.**
- All staff had access to a policy folder which contained paper copies of the providers policies. We found policies and procedures were not routinely updated, version controlled and that they were mixed with older out of date policies.
- The provider did carry out some audits, for example scan quality, patient attendance and reason for attending clinics. However, there was no agreed audit system used to establish if care and treatment was in line with evidenced based care and treatment.
- The provider maintained a dedicated staff folder which contained up to date guidance from the National Institute for Health and Care Excellence (NICE), the British Medical Ultrasound Society, Royal College of Obstetricians and Gynaecologists and the Society of Radiographers.

Nutrition and hydration

- Staff had access to a selection of refreshments (tea, coffee and water) which they provided patients in some circumstances if it was safe to do so. During our inspection, we observed staff providing a patient and their relatives with warm drinks and biscuits and routinely offering patients drinks on arrival.

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 are pain free. They did use additional pillows and altered positions to aid patient comfort.

Patient outcomes

- The nominated individual showed us evidence of completing rescan audits for their areas of responsibility. The audits included suggested recommendations for improvements prior to the next annual audit.
- The records audit from October 2018 which looked at quality of ultrasound scans produced and the quality of the reports produced by sonographers. All sonographers were producing scans and reports of reasonable or high quality. No sonographer had produced reports or scans of poor quality.
- The nominated individual told us that monitoring patient outcomes for the service was difficult, but they did use patient feedback to monitor patient outcomes, for example if their birth had gone onto to be successful, or if they had not been happy with the support or treatment outcomes.

Competent staff

- **The service made sure staff were competent for their roles. Managers appraised staff's work performance to provide support and monitor the effectiveness of the service.**
- The service offered staff continuous learning opportunities to enhance their current roles and we noted evidence that staff had attended national and international conference to update their skills and knowledge.
- The service had a recruitment process in place for all new staff, this included checking references, passports, entitlement to work in the UK and disclosure and barring service checks (DBS). The provider did not have a central record for DBS checking or any reference to how often the DBS would be checked. The provider informed us that the staff were on an annual DBS subscription and this was checked annually, all DBS certificates were up to date at the time of our inspection.

Requires improvement

Diagnostic imaging

- Sonographers were registered with a professional body, either the Health and Care Professionals Council (HCPC) or or they were registered with the Nursing and Midwifery Council (NMC) as one sonographer had an employment history as a midwife.
- 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. However, the nominated individual said 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% of staff had received an appraisal within the last 12 months.

Multidisciplinary working

- **Staff of different roles worked together as a team to benefit patients.**
- This was a small service, however we observed that working relationships between clinical and reception staff were extremely positive and professional. Staff worked well together to place the patients at the centre of service and this was evident in the patient feedback.

Seven-day services

- 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 clinic any day of the week.
- The timings that were offered to patients were also arranged to try and ensure appointments were available to cover morning, afternoon and evening demand.

Health promotion

- The provider had health promotion literature available within its reception area, including information on various forms of cancer, local support groups and alternative treatments.
- The providers web site also offered a range of complementary services to support patients with their existing conditions.

Consent and Mental Capacity Act

- **Staff were aware of the importance for gaining consent from patients before conducting any procedures. We observed staff gaining consent from patients prior to starting their ultrasound scan.**
- The provider 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 provider did not have a Mental Capacity Act 2005 (MCA) or Deprivation of Liberty Safeguards 2009 (DoLS) policy in place. It had a statement within its safeguarding policy to offer staff some guidance on the MCA principles. Mental Capacity Act training was completed as part of mandatory training and all staff had completed mandatory training on the MCA.
- The provider had a policy on consent and on privacy, however this did not relate to 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 consent form.

Are diagnostic imaging 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

Diagnostic imaging

- **Staff cared for patients with compassion. Feedback from patients confirmed that staff treated them well and with kindness**.
- During our inspection, we spoke with five patients and their relatives following their treatment at the clinic. All feedback about the service was positive with comments including "Made me feel happy and relaxed", and "Would recommend to a friend". Another patients feedback said, "Our experience with you was truly magical, more than we would have ever expected" and another said, "Had a positive experience with you and we will visit you again with pleasure".
- The service routinely gathered patient feedback and attached a patient feedback form with its reports to patients to encourage them to leave feedback. The provider published feedback on their website and encouraged patients to leave feedback after each appointment.
- Between June 2018 and August 2018, the provider collected 199 patient questionnaires. The results relating to reception staff showed 99.9% of patients said they were polite, 91.4% said they were professional and 86.43% said they were helpful. The results showed 100% of patients found sonographers to be professional, 80% said they were reassuring and 60% said they had good communication skills. The provider had an annual review document where it identified actions to address any shortfalls.
- Staff saw a range of patients, some of whom had a history with the service and some who were attending for a first appointment. We observed staff treating all patients compassionately and empathetically. Staff would not rush patients who were nervous or upset prior to or during the procedure. The staff provided care that was patient centred and patients clearly appreciated this.
- The provider did not have a specific policy for the use of chaperones. However, the provider told us that patients could request a chaperone as part of the booking process and that reception staff would ask if they needed additional support. The provider ensured that if they were scanning male testes this was always done with two staff present in the clinical area.

Emotional support

- **Staff provided emotional support to patients to minimise their distress.**
- The provider had a separate private office that could be used for giving any bad news. The office had a separate door which led to the exterior of the building so that patients could leave without having to go back through the reception area if they were distressed.
- Staff understood the impact that ultrasound scans on patients' wellbeing, especially if concerning or unexpected findings were discovered during the scan.
- During our inspection we observed staff being kind, thoughtful, supportive and offering 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 "Made them feel confident and enjoy the experience".
- If staff recognised patients required additional support, they signposted them to organisations and charities which would be able to do this. One example staff gave was voluntary charitable service that provided additional support to staff.
- At the end of all procedures, patients were always given advice of what to do if they had concerns around their health and wellbeing. Patients, attending for pregnancy scans, were 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 general practitioner if they had concerns following the scan.

Understanding and involvement of patients and those close to them

- **Staff involved patients and those close to them in decisions about their care and treatment.**
- We observed staff taking the time with patients to explain the details of the ultrasound scan they were having 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.
- 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, patients told us that staff were professional and allowed them time and explained activities clearly to them.

- At the end of the scan, staff went over 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 approach 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.
- 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 payment were completed sensitively before the ultrasound scan took place. This also enabled staff to check what patients understood about the scan they were booked in for and their reasons for requesting the scan.

Are diagnostic imaging services responsive?

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 planned and provided services in a way that met the needs of local people.**
- The providers location was appropriate to meet the needs of the patients who attended for ultrasound scans. It was situated off a main road, had ample free parking and easy access due to its single level layout with no steps.
- The provider facilities were child friendly and welcomed families to bring children of all ages along to appointments. The reception had a selection of wipeable toys which children could play with.
- The service offered a range of appointment times and days to meet the needs of the patients who used the service. The nominated individual told us there was mixed demand for appointment times and they would offer appointments later in the day and at weekends.
- Appointments were booked using the providers website or patients could ring the reception staff who would book them into an appointment which best suited their requirements.

Meeting people's individual needs

- **The service took account of patients' 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 clinic for an ultrasound who had complex needs. If services were provided staff would ensure the patient's needs were met and carers or relatives could stay with the patient. The provider could also extend appointment times to ensure patients were not rushed causing the patient less distress.
- Staff did not have access to a translation and interpretation service for patients whose first language was not English. However, many of the staff were multi lingual and used their language skills to support patients. Staff also encouraged family members to attend appointments if language may be an issue.
- The reception had information for patients to take away with them. Leaflets were only available in English, and were only available in standard print. Staff told us they could access leaflets in other language if necessary, but most patients usually brought a family member or friend to the appointments to help communication.

Requires improvement

Diagnostic imaging

- The provider could meet the needs of bariatric patients. The couch used for ultrasounds was able to take the weight of patients who weighed up to 28 stones. There was no additional hoisting equipment so patients would only be seen if they were able to stand and transfer themselves to the treatment couch.

Access and flow

- **People could access the service when they needed it.**
- Most appointments were arranged within a day or two of the patient contacting the service, or within a timeframe which suited them. However, there was also the opportunity to book appointments for the same day.
- The provider monitored DNA (did not attend) appointments. If patients needed to change their appointments they would contact the service and the provider would offer an alternative appointment or offer a refund of the deposit (reason for cancellation and length of notice dependant).
- Patients who attended an ultrasound scan were given a copy of any significant measurements taken during the procedure at the end of their appointment.
- Between January 2018 and October 2018, data from the provider during the inspection showed that 139 patients cancelled appointments, the main reason was for pregnancy scan cancellations due to a miscarriage. Twenty patients did not attend for appointments. The provider did try and follow up on these via email and telephone calls, but this was often not successful and patients did not contact the provider for follow up appointments. The provider did not cancel any appointments.

Learning from complaints and concerns

- **The service treated concerns and complaints seriously, investigated them and learned lessons from the results, and shared these with all staff.**
- The service had a complaints policy in place, which was last updated in February 2017 and due for renewal in February 2019. This provided staff with the details of action to take if a complaint was made either by telephone or email.
- The service recorded one complaint between upheld by the service.
- All complaints and negative feedback received on the electronic feedback service were treated with the same level of importance. The nominated individual had oversight of the complaints which came through and ensured the complaints process was followed correctly and completely.

Complaints were investigated by the nominated individual. All complaints were responded to within seven working days. The nominated individual would respond to patients usually by telephone or by email, determined by the patients preferred method of contact.

Are diagnostic imaging services well-led?

Requires improvement

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 **requires improvement.**

Leadership

- **Managers of the service had the right skills and abilities to run a service, however risk and audit were not embedded within the leadership of the service.**
- The nominated individual led the service with a registered manager, and employed a receptionist and two sessional sonographers. At the time of our inspection the registered manager was on an indefinite period of leave and we advised the nominated individual to report this to CQC in the usual reporting framework. The provider did inform us of the registered managers absence immediately following inspection.
- Staff spoke positively about the nominated individual, saying they were approachable and always willing to offer advice and guidance.
- The nominated individual maintained their skills and knowledge through continuing with clinical practice.

This demonstrated to staff their clinical currency and demonstrated positive role modelling. The nominated individual often sat in in scans and encouraged other staff to observe their practice.

Vision and strategy

- **The service had a vision for what it wanted to achieve.**
- The provider had a vision to provide quality care from expertsStaff we spoke with all felt they were aiming towards providing a high-quality and expert service.

Culture

- **Managers promoted a positive culture that supported and valued staff, creating a sense of common purpose based on shared values.**
- Staff during our inspection spoke of a positive place to work where staff shared information and worked together well to meet the needs of the patients.
- The provider 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 and managers had dealt appropriately with any incidents which met the criteria where formal duty of candour required implementing.

Governance

- **The service did not systematically improve service quality and there was a lack of overarching governance.**
- The nominated individual and registered manager had a monthly meeting with the both sonography staff to discuss the future of the service and any issues impacting on business continuity. Feedback and minutes from these meetings was available to the rest of the team.
- The provider ensured that it carried out the necessary recruitment checks prior to staff starting employment. It had recently engaged an external consultancy to manage its health and safety, employment and risk management processes to ensure consistency.
- While each of the four staff members had a personnel file, the files were not in any specific order and the provider had no routine method of checking when staff training required renewal or when a disclosure and barring service (DBS) check was required.
- The provider had no system for maintaining policies and procedures to ensure they were up to date, version controlled and met national guidance. We found a number of polices for example, incidents, staff sickness and safeguarding adults that were not up to date, or version controlled. We also found the provider did not have a policy for the safeguarding of children, despite the service seeing patients under 18 years of age.

Managing risks, issues and performance

- **The service did not have systems to identify risks, plan to eliminate or reduce them.**
- The provider did carry out individual risk assessments to ensure patient safety, environmental safety and equipment safety.
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  The providers incident reporting policy was inadequate for the service and did not reflect the level of risks within the service.
- Between April 2018 to December 2018 the service performed five ultrasound scans on children and two pregnancy related scans on patients under 18 years of age. However, this part of the service was not within the providers statement of purpose and no guidance to the public was available for this service.
- The provider did complete some audits, for example image scan quality. However, there was no planned audit process that would enable to the provider to measure the quality of its service or make improvements on any areas of weakness.
- The provider did measure some areas of performance, for example how many patient appointments were cancelled or not attended and patient feedback. The provider had used this feedback to make some improvements in its services, for example introducing IT to store patient records and improve communication with patients.

Requires improvement

Diagnostic imaging

- Patients had access to the providers terms and conditions via the providers website when making a booking. If a phone booking was received a copy of the terms and conditions would be emailed to the patient.
- Payment was taken securely by the provider electronically at the time of the appointment.
- Staff relied on the external company to alert them as to when the next equipment service was due.

Engagement

- **The service engaged well with patients, staff, and the public.**
- The service 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 on their experience. 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 on any concerns.
- The service completed their own internal patient feedback survey on an annual basis. The last survey was between June and August 2018 and it showed most patients were happy with the professionalism of the staff, but communication could be improved. The provider had acknowledged this and made recommendations to improve the service, but we did not see an action plan in place to address any shortfalls.

Learning, continuous improvement and innovation

- The provider had introduced a new IT system to store and retrieve patient records and reduce the risk of information governance breaches.

Outstanding practice and areas for improvement

Areas for improvement

Action the provider MUST take to improve

- The provider must ensure that its systems for the management and referral of safeguarding concerns reflect current best practice in relation to safeguarding adults and that all staff understand how to make an adult safeguarding referral.
- The provider must ensure that it implements a safeguarding children policy and all staff receive specific guidance on the policy and how to make a children's safeguarding referral.
- The provider must ensure it updates its incident reporting policy and procedures and report safety incidents appropriately.
- The provider must ensure its statement of purpose reflects all its service activity and how it meets the needs of patients under 18 years of age.
- The provider must ensure it implements a system to systematically improve service quality and governance.

Action the provider SHOULD take to improve

- The provider should ensure it uses additional resources to support patients who may not use English as a first language.

This section is primarily information for the provider

Requirement notices

Action we have told the provider to take

The table below shows the legal requirements that were not being met. The provider must send CQC a report that says what action they are going to take to meet these requirements.

Regulated activity	Regulation
Diagnostic and screening procedures	Regulation 17 HSCA (RA) Regulations 2014 Good governance The Health and Social Care Act 2008 (Regulated Activities) Regulations 2014 Regulation 17. 17. (1) Systems or processes must be established and operated effectively to ensure compliance with the requirements in this Part. (2) Without limiting paragraph (1), such systems or processes must enable the registered person, in particular, to— (a) assess, monitor and improve the quality and safety of the services provided in the carrying on of the regulated activity (including the quality of the experience of service users in receiving those services);