

Take A Peek Limited

Quality Report

Take A Peek Limited 31-33 Lynton Way Windle St Helens Mersevside **WA10 6EQ** Tel: 01744 610417 Website: www.takeapeek3d.com

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

Ratings

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

Overall summary

Take A Peek Limited is operated by Take A Peek Limited. The service is located in St. Helens, Merseyside and provides a range of diagnostic ultrasound scan services for private fee paying pregnant women of all ages.

The main service provided by the service is diagnostic imaging. We inspected this service using our comprehensive inspection methodology on 13 May 2019. To get to the heart of patients' experiences of care and treatment, we ask the same five questions of all services: are they safe, effective, caring, responsive to people's needs, and well-led? Where we have a legal duty to do so we rate services' performance against each key question as outstanding, good, requires improvement or inadequate.

Summary of findings

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

This is the first time we have rated this service. We rated it as Good overall.

We found the following areas of good practice:

- The service had enough staff to care for patients and keep them safe. Staff had training in key skills, understood how to protect patients from abuse, and managed safety well.
- The service controlled infection risk well. Staff kept good care records. The service managed safety incidents well and learned lessons from them.
- Staff provided good care and treatment. Managers monitored the effectiveness of the service and made sure staff were competent.
- Staff worked well together for the benefit of patients, supported them to make decisions about their care, and had access to good information.
- Staff treated patients with compassion and kindness, respected their privacy and dignity, took account of their individual needs, and helped them understand their conditions. They provided emotional support to patients, families and carers.
- The service planned care to meet the needs of local people, took account of patients' individual needs, and made it easy for people to give feedback.
- People could access the service when they needed it and did not have to wait too long for treatment. The service treated concerns and complaints seriously, investigated them and shared lessons learned with all
- Leaders had the integrity, skills and abilities to run the service. Staff understood the service's vision and values, and how to apply them in their work. Staff felt respected, supported and valued. They were focused on the needs of patients receiving care.
- Staff were clear about their roles and accountabilities. The service engaged well with patients and the community to plan and manage services and all staff were committed to improving services continually.

However, we also found the following issues that the service provider needs to improve:

- The service did not have effective governance arrangements in place to ensure high standards of care were maintained at all times.
- Policies and procedures did not always include version controls or review dates. Sufficient staff recruitment checks had not been carried out for all staff.
- Risks had not been effectively managed in areas such as staff recruitment checks, monitoring of staff training requirements, management of policies and procedures and lack of professional indemnity insurance arrangements. Staff did not keep documented records of risk assessments for each patient.
- There was no documented audit or monitoring in place to cover staff recruitment files, mandatory training compliance and overall governance processes and policies.
- Staff had completed mandatory training in key skills; however the service did not have an effective system in place to identify training needs and monitor compliance for all staff.
- The service did not have any spill kits for cleaning up spills from bodily fluids.
- The service did not have processes in place for staff appraisal or supervision meetings in order to provide support and monitor the effectiveness of the service
- Not all staff had completed equality and diversity training and there was no information available for patients that were unable to speak English.

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

Ann Ford

Deputy Chief Inspector of Hospitals (North Region)

Summary of findings

Our judgements about each of the main services

Summary of each main service Service Rating

Diagnostic imaging

Diagnostic imaging was the main activity provided by the service.

We rated this service as good overall.

We rated this service as good for safe because they had enough staff to care for patients and keep them safe. Staff understood how to protect patients from abuse, and managed safety incidents and infection risks well. We rated this service as good for caring and responsive because feedback from patients about the service was positive and services were planned and delivered to meet the needs of patients.

We rated this service as requires improvement for well-led because the service did not have effective systems in place for governance and risk management.

We do not rate effective for diagnostic imaging services.

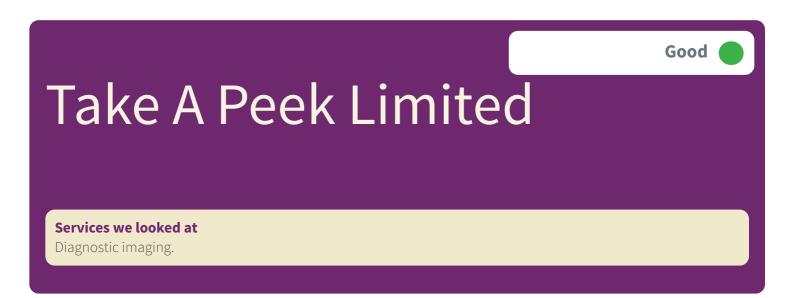


Summary of findings

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Background to Take A Peek Limited

Take A Peek Limited is a private diagnostic imaging located in St. Helens, Merseyside and is operated by Take A Peek Limited. The service provides pregnancy ultrasound services to self-funding pregnant women of all ages. All ultrasound scans performed at Take A Peek Limited are in addition to those provided through the NHS.

The service has been registered with the Care Quality Commission (CQC) since March 2011 to provide the regulated activity of diagnostic and screening procedures. It has had a registered manager in post since registering with the CQC in March 2011.

There were no special reviews or investigations of the service ongoing by the CQC at any time during the 12 months before this inspection. The service was previously inspected in November 2013. We found that the service was meeting all standards of quality and safety it was inspected against during that inspection.

Our inspection team

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

Information about Take A Peek Limited

Take A Peek Limited provides pregnancy ultrasound services to self-funding pregnant women of all ages. All ultrasound scans performed at Take A Peek Limited are in addition to those provided through the NHS. The scan procedures offered include: -

- Early assurance scans (at seven to 14 weeks pregnancy to establish heart beat and expected due date)
- Sexing scans (at 15 to 16 weeks pregnancy to determine gender). This service is offered as 2D (black and white) scan at 15 weeks and 4D (colour) scan at 16 weeks pregnancy.
- A 2D (black and white) scan is offered at 24 weeks pregnancy to check baby growth and any anomalies.
- The high definition / 4D scans are offered to patients at 28-30 weeks pregnancy. However patients could attend for scans any time between 24 – 34 weeks pregnancy.

The service is located on the ground floor. It has a reception area with a large waiting area and one treatment room where scan procedures can be carried out in privacy. There is also a toilet for patients and visitors to use.

We inspected this service using our comprehensive inspection methodology on 13 May 2019. We looked at the treatment room and reception and waiting areas as part of the inspection. We spoke with one receptionist and the registered manager (who was also a sonographer). We spoke with four patients and two relatives. During our inspection, we reviewed eight sets of patient records.

Activity (March 2018 to April 2019)

• In the reporting period there were 4,203 scan procedures recorded. This included 10 scan procedures performed on patients under 18 years of age.

The service is operated by three sonographers (including one that is also a registered midwife), supported by four part-time reception staff.

Track record on safety (March 2018 to April 2019)

- No Never events
- No serious injuries
- There were six clinical incidents reported by the service. These were all classed as 'no harm'.

- No incidences of hospital acquired Meticillin-resistant Staphylococcus aureus (MRSA),
- No incidences of hospital acquired Meticillin-sensitive staphylococcus aureus (MSSA)
- No incidences of hospital acquired Clostridium difficile (c.diff)
- No incidences of hospital acquired E-Coli
- Three complaints

The five questions we ask about services and what we found

We always ask the following five questions of services.

Are services safe?

This is the first time we have rated this service. We rated safe as good.

We found the following areas of good practice:

- The service had enough staff with the right qualifications, skills, training and experience to keep people safe from avoidable harm and to provide the right care and treatment.
- Staff understood how to protect patients from abuse and the service worked well with other agencies to do so.
- The service controlled infection risk well. Staff used equipment and control measures to protect patients, themselves and others from infection.
- The design, maintenance and use of facilities, premises and equipment kept people safe.
- Staff kept detailed records of patients' care and treatment. Records were clear, up-to-date, stored securely and easily available to all staff providing care.
- The service managed patient safety incidents well. Staff recognised and reported incidents and near misses. Managers investigated incidents and shared lessons learned with the whole team.

However, we also found the following issues that the service provider needs to improve:

- Staff had completed mandatory training in key skills; however the service did not have an effective system in place to identify training needs and monitor compliance for all staff.
- The service did not have any spill kits for cleaning up spills from bodily fluids
- There were processes in place to assess and manage some patient risks. However, staff did not keep documented records of risk assessments for each patient.

Are services effective?

We inspect but do not rate effective for diagnostic imaging services.

We found the following areas of good practice:

- The service provided care and treatment based on national guidance and evidence of its effectiveness. Managers checked to make sure staff followed guidance.
- Managers monitored the effectiveness of care and treatment and used the findings to improve them.

Good



- Staff worked together as a team to benefit patients. They supported each other to provide good care.
- Staff supported patients to make informed decisions about their care and treatment. They followed national guidance to gain patients' consent.

However, we also found the following issues that the service provider needs to improve:

 The service did not have processes in place for staff appraisal or supervision meetings in order to provide support and monitor the effectiveness of the service.

Are services caring?

This is the first time we have rated this service. We rated caring as good.

We found the following areas of good practice:

- 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?

This is the first time we have rated this service. We rated responsive as good.

We found the following areas of good practice:

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

However, we also found the following issues that the service provider needs to improve:

The service took account of patients' individual needs.
 However, not all staff had completed equality and diversity training and there was no information available for patients that were unable to speak English.

Good

Good

Are services well-led?

This is the first time we have rated this service. We rated well-led as requires improvement.

We found the following issues that the service provider needs to improve:

- The service did not have effective governance arrangements in place to ensure high standards of care were maintained at all times.
- Policies and procedures did not always include version controls or review dates. Sufficient staff recruitment checks had not been carried out for all staff.
- The service did not have effective systems in place to identify risks, plan to eliminate or reduce them, and cope with both the expected and unexpected.
- Risks had not been effectively managed in areas such as staff recruitment checks, monitoring of staff training requirements, management of policies and procedures and lack of professional indemnity insurance arrangements.
- There was no documented audit or monitoring in place to cover staff recruitment files, mandatory training compliance and overall governance processes and policies.

However, we also found the following areas of good practice:

- The service had a vision for what it wanted to achieve and workable plans to turn it into action, which it developed with staff.
- Managers had the right skills and abilities to run a service providing high-quality sustainable care.
- Managers promoted a positive culture that supported and valued staff, creating a sense of common purpose based on shared values.

Requires improvement



Detailed findings from this inspection

Overview of ratings

Our ratings for this location are:

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



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

Are diagnostic imaging services safe? Good

This is the first time we have rated this service. We rated safe as good.

Mandatory training

- The service provided mandatory training in key skills to all staff; however the service did not have an effective system in place to identify training needs and monitor compliance for all staff.
- The service did not have a formal policy in place to outline the training requirements for staff working within the service. There was no system in place that defined the type of training required for each staff, the frequency of this training and how training completion would be monitored.
- The three sonographers (including the registered manager) working at the service also worked in substantive posts in NHS acute trusts. The registered manager told us the sonographers completed mandatory training in their NHS organisations and this training was deemed sufficient for their role in this service.
- The registered manager told us they sought assurance on mandatory training completion through informal confirmation by the three sonographers at routine director's meetings. However, the service did not maintain records to provide assurance that mandatory training compliance was maintained for the three sonographers.
- The provider submitted evidence following the inspection that demonstrated all three sonographers had up to date mandatory training gained through their

NHS roles during the past year. The mandatory training covered topics such as health and safety, fire safety, infection prevention and control, information governance, equality and diversity, moving and handling, adult and children's safeguarding training and resuscitation training.

- The provider submitted evidence following the inspection that all the reception staff (four individuals) had completed adult and children's safeguarding (level two) and basic life support and resuscitation training (for both adults and children). One receptionist had also completed training in data security and infection prevention and control.
- The registered manager told us the reception staff did not complete any other mandatory training. We found the service was able to demonstrate that some patient safety risks were managed through completion of safeguarding and resuscitation training.
- The registered manager told us they had considered the training requirements for the reception staff and felt that mandatory training in safeguarding and life support was sufficient for the role.
- We found that none of the reception staff had completed formal mandatory training in areas relevant their role, such as training in information governance or equality and diversity. However, there was a competency assessment for reception staff that included aspects of equality and diversity and information governance.

Safeguarding

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



- There were policies in place for safeguarding vulnerable adults and safeguarding children and young people that provided guidance for staff on how to identify and report safeguarding concerns.
- Staff received mandatory training in safeguarding adults and children. All the sonographers and reception staff had completed level one and level two safeguarding training (adults and children). Two of the sonographers had also completed children's safeguarding (level three) training.
- The training was in line with Intercollegiate Document 'Safeguarding Children and Young People: Roles and Competencies for Healthcare Staff Fourth edition: January 2019'. This stated that diagnostic radiographers required a minimum of level 2 training, but those involved full time or significantly in paediatric radiography or involved in imaging for suspected physical abuse required level three training. The service had only carried out a limited number of scans for patients under 18 years of age (10 cases in the past 12 months).
- The staff we spoke with were aware of how to identify abuse and report safeguarding concerns. The service had a document which contained details of the local authority safeguarding teams across the region. The receptionist told us they would notify the sonographer on duty if they identified any safeguarding concerns and the sonographer would report the concerns to external organisations such as the Police or relevant local authority.
- The service reported one safeguarding incident during the past 12 months. This was reported in March 2019 and related to matters outside of the service. We saw evidence that staff had taken appropriate actions to protect the patient from potential abuse and an appropriate local authority safeguarding referral had been made.
- The registered manager told us they did not provide training in female genital mutilation (FGM) because the service did not carry out invasive scans and it would be difficult to identify this in patients that underwent scans. However, the registered manager had a good understanding and awareness of female genital mutilation.

Cleanliness, infection control and hygiene

 The service controlled infection risk well. Staff used equipment and control measures to protect

patients, themselves and others from infection. They kept equipment and the premises visibly clean. However; the service did not have any spill kits for cleaning up spills from bodily fluids.

- There were no cases of Meticillin-resistant
 Staphylococcus aureus (MRSA) bacteraemia,
 Methicillin-sensitive Staphylococcus aureus (MSSA)
 bacteraemia, Clostridium difficile (C.diff) or Escherichia coli (E. coli) reported by the service between March 2018 and April 2019.
- The treatment room, reception and waiting area and the toilet area were visibly clean and tidy. There was an infection control policy in place and the three sonographers and two of the four receptionists had completed infection, prevention and control training.
 One of the sonographers was the infection control lead for the service.
- Cleaning schedules and daily checklists were in place and the cleaning schedules we looked at were complete and up to date. The sonographers were responsible for cleaning the environment and cleaning and decontaminating the ultrasound equipment within the treatment room.
- Staff used detergent wipes and chlorine-based disinfectant to clean and decontaminate surfaces and equipment. The ultrasound machine probe was cleaned and disinfected on a daily basis and in-between patient use.
- The cleanliness of the environment and equipment was checked as part of the provider's annual quality assurance audit. The service achieved 100% compliance for infection control and equipment in the most recent quality audit (for December 2018).
- Personal protective equipment, such as gloves and aprons, were readily available. There were enough hand wash sinks and hand gels. Staff we saw were compliant with hand hygiene and 'bare below the elbow' guidance.
- The registered manager told us they did not routinely carry out hand hygiene audits due to the small size of the team. However, following the inspection the provider submitted evidence to show a hand hygiene audit had been carried out following the inspection and 100% compliance was achieved. The registered manager reported that the hand hygiene audit would be carried out at least annually in the future.
- The service did not have any spill kits for cleaning up spills from bodily fluids (such as vomit) and there were



no specific arrangements for the disposal of clinical waste. The registered manager told us all waste was disposed of as general waste and if there was any contaminant waste (such as bodily fluids), then they would double-bag and dispose along with routine domestic waste.

 There was a risk assessment in place for bodily fluid spillages that had been completed in May 2015. This identified controls to manage the risks of exposure to patients and staff such as use of personal protective equipment and detergent wipes for cleaning and decontaminating spillages. The registered manager told us they had not had any instances of bodily fluid spillage instances between March 2018 and April 2019.

Environment and equipment

- The design, maintenance and use of facilities, premises and equipment kept people safe. Staff were trained to use them.
- The service was located on the ground floor and was easily accessible to patients and visitors. The entrance was secure with a locked door and access to the service was controlled by the reception staff.
- The reception area and main waiting area was spacious and well maintained and provided a comfortable environment for patients and visitors. There was also a toilet for patients and visitors to use.
- There was one treatment room where scan procedures could be carried out in privacy. The treatment room contained an adjustable couch and had adequate seating for those who accompanied patients to their appointment.
- Consumable items, cleaning equipment and personal protective equipment were stored in cabinets in the treatment room. The service had one static ultrasound machine located in the treatment room and this was also connected to a large television screen in the room projected the images from the ultrasound machine for patients and those accompanying them to view.
- The sonographers carried out daily checks on the ultrasound equipment before and after use. There was also a monthly quality check carried out that included image uniformity checks, checks for visible damage to equipment and integrity of cables, transducer seal checks and checks for error messages and fault logs. Records from January 2018 to May 2019 showed these checks were carried out on a monthly basis and no issues had been identified.

- There was an arrangement in place with an external contractor to service and maintain the ultrasound equipment on an annual basis. Service records showed the ultrasound machine was last serviced in August 2018. The registered manager told us the external service contractor would be contacted if there were any equipment issues or faults and the equipment would be replaced as part of the service contract if it could not be repaired. There had been no faults or equipment issues reported by the service during the past 12 months.
- We saw evidence that electrical safety testing had been carried out on all electrical equipment within the past 12 months. The registered manager told us the premises were leased and there was a contractual arrangement with the landlord for the servicing and maintenance of auxiliary systems (such as gas, fire safety, electric and water supplies).
- There were suitable arrangements in place for fire safety, including a fire risk assessment and clear instructions for staff to follow in the event of a fire.
- There was a first aid kit available. However, the service did not have any emergency equipment, emergency medicines or kits on site.

Assessing and responding to patient risk

- There were processes in place to assess and manage some patient risks. However, staff did not keep documented records of risk assessments for each patient.
- The service did not have defined specific admission or exclusion criteria for patients. All the patients that used the service were self-referred private fee paying patients which meant most patients were low risk, healthy patients that did not have complex health needs.
- Staff clearly explained to patients verbally and in writing that the services offered were in addition to and not a substitute for their routine NHS pregnancy scans.
- The registered manager told us patient risks such as medical history, pregnancy history, allergy status and infection status were discussed with the patient and they relied on patients to disclose this information verbally during discussions with staff. We saw evidence that patients risks were discussed with one patient we observed during the inspection. However, there was no formal documented risk assessment conducted for patients prior to undergoing scan procedures to ensure a consistent approach to identifying and assessing patient risks.



- The service only used latex free gloves to minimise the risks for patients that had an allergy to latex.
- There were clear processes in place to escalate unexpected or significant findings identified during ultrasound scans. Where any concerns were identified, this was explained to the patient and they were provided with a scan report to take with them.
- The registered manager told us patients were advised to contact their general practitioner (GP), midwife or local early pregnancy unit if the scan procedures identified any abnormalities. The sonographers had contact details for early pregnancy units across North West region and directly referred patients if any serious concerns were identified during the scan procedure.
- The service reported that there had been a total of 69 referrals to NHS services made between March 2018 and April 2019 as a result of unexpected findings during scan procedures.
- To improve the safety for patients undergoing ultrasound scans, the British Medical Ultrasound Society (BMUS) produced a 'paused and checked' checklist to be used as guidance for sonographers during each scan procedure. This included checks such as confirming the patient's identity and consent; providing clear information and instructions, including the potential limitations of the ultrasound scan; following the BMUS safety guidelines; and informing the patient about the results. A poster displaying information on this was displayed in the scan procedure room.
- The registered manager told us the 'paused and checked' checklist was followed for all scan procedures by the sonographers. We observed staff complete the checklist during the scan procedure we observed. We saw the checks were completed but not recorded during the scan we observed.
- We saw evidence to show all the sonographers and reception staff had completed basic life support training for adults and children.
- The registered manager told us they would contact the emergency services if a patient's health deteriorated whilst on site so the patient could be transferred to the nearest acute hospital by ambulance. There had been no instances where a patient's health deteriorated and required urgent transfer to hospital between March 2018 and April 2019.

Diagnostic imaging staffing

- The service had enough staff with the right qualifications, skills, training and experience to keep people safe from avoidable harm and to provide the right care and treatment.
- The service was managed by three directors, consisting
 of the registered manager (who was a sonographer) and
 two other sonographers. The sonographers were
 supported by four reception staff that worked on a
 part-time basis.
- Scan procedures were only carried out by the sonographers. There was at least one sonographer and a receptionist on site when patients attended the service.
- There were no staff vacancies at the time of our inspection. The registered manager told us they did not use agency staff and cover for leave or sickness was provided by the existing team.

Medical staffing

The service did not employ any medical staff.

Records

- Staff kept detailed records of patients' care and treatment. Records were clear, up-to-date, stored securely and easily available to all staff providing care.
- Patient records consisted of paper-based consent forms and electronic scan images and test reports. We looked at the records for eight patients and found these were complete and up to date.
- The consent forms detailed the risk and benefits of the procedure and terms and conditions of the service, which patients were asked to read, sign and date before any ultrasound scan was undertaken.
- Scan reports were recorded and stored electronically.
 These included the patient's identification, the gestation period (the number of weeks of their pregnancy) and the ultrasound images as well as the findings and recommendations.
- The paper consent forms were stored securely in a locked cupboard and scanned onto a desktop PC for every attendance. The paper copies were cross shredded at the end of each day following checks by reception staff to confirm the consent form had been correctly scanned in. The electronic copy consent forms were kept on the PC until the end of the calendar month after which the data was transferred onto a CD-ROM and then stored in a locked cabinet for archive purposes.



- Scan images were stored on the ultrasound machine for up to three months and then removed and archived on an external hard-drive. All scanned consent forms, archived images were kept for at least 25 years.
- Where an abnormality was detected after a scan was performed, the images were stored on the ultrasound machine and downloaded onto an encrypted USB and stored in a locked cabinet for archive purposes. A written report was also given to the patient.

Medicines

 The service did not store, prescribe, or administer any medicines.

Incidents

- The service managed patient safety incidents well.
 Staff recognised and reported incidents and near misses. Managers investigated incidents and shared lessons learned with the whole team and the wider service. When things went wrong, staff apologised and gave patients honest information and suitable support.
- There was an incident reporting policy that outlined the process for identifying and reporting clinical and non-clinical incidents and near misses. Staff were aware of the process for reporting any identified risks to patients, staff and visitors. All incidents were logged using a paper-based incident reporting form.
- There had been no never events or serious patient safety incidents reported by the service between March 2018 and April 2019. A never event is a serious incident that is wholly preventable as guidance, or safety recommendations providing strong systemic protective barriers, are available at a national level, and should have been implemented by all providers. The event has the potential to cause serious patient harm or death, has occurred in the past and is easily recognisable and clearly defined.
- There had been six clinical incidents reported between March 2018 and April 2019. These were all classed as 'no harm' incidents and mainly related to deviations in scan procedures or untoward findings during scan procedures. There were no non-clinical incidents reported during this period.
- The registered manager maintained a file containing each incident report and details of remedial actions taken. We looked at the incident records and found

- these were reviewed and investigated and remedial actions taken had been documented. Incidents were reviewed by staff with the appropriate level of seniority, such as the registered manager or a sonographer.
- The registered manager told us incidents were shared with staff to improve practice and the service to patients. Meeting minutes showed that incidents were discussed during routine staff meetings so shared learning could take place.
- The registered manager was aware of their responsibilities regarding duty of candour legislation.
 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.
- There had been no incidents reported by the service that met the threshold for implementing the duty of candour.
- The registered manager was aware of their responsibility to report notifiable incidents to the Care Quality Commission (CQC) and other external organisations.

Safety Thermometer (or equivalent)

- The service did not maintain a clinical dashboard for patient safety incidents.
- There had been no incidents that had led to patient harm or any patient safety incidents (such as falls with harm) reported by the service between March 2018 and April 2019.

Are diagnostic imaging services effective?

We inspect but do not rate effective for diagnostic imaging services.

Evidence-based care and treatment

- The service provided care and treatment based on national guidance and evidence of its effectiveness.
 Managers checked to make sure staff followed guidance.
- Diagnostic ultrasound scan procedures were carried out in accordance with national guidelines such as from the British Medical Ultrasound Society (BMUS) the Society of



Radiographers (SCoR) and the European Federation of Societies for Ultrasound in Medicine and Biology (EFSUMB). Staff also followed NHS fetal anomaly screening programme (FASP) guidelines.

- The service had clinical standard operating procedures in place that provided staff with guidance on conducting ultrasound scan procedures at specific stages of pregnancy and for identifying any anomalies. These were based on national guidelines and included revision histories and review dates ranging between one to three years. The standard operating procedures we saw were all up to date and within their specified review dates.
- The registered manager maintained the standard operating procedures. The registered manager told us the sonographers benchmarked against national guidelines and updated these procedures following any changes to best practice guidelines as part of routine director's meetings.
- The sonographers did not use colour doppler imaging during early pregnancy scans. This was in line with British Medical Ultrasound Society (BMUS) guidelines.
- There was clear information given to patients that the service performed diagnostic scans (such as to identify the gender of the baby or any anomalies) and scans were not performed solely for souvenir or keep sake purposes. This was in line with British Medical Ultrasound Society (BMUS) guidelines.

Nutrition and hydration

- The service provided diagnostic ultrasound scan procedures and hydration and nutrition assessments were not routinely carried out due to the nature of the services provided.
- There were no prerequisite requirements for patients (such as fasting) in relation to scan procedures.
- Patients were only present on site for a short period of time, therefore food and drink not routinely offered; however water was available in waiting area for patients and visitors.
- Patients were given information about nutrition and hydration verbally and in leaflets and there was information on the provider's website on how to manage pregnancy including nutrition and hydration advice.

Pain relief

- Staff did not routinely assess pain symptoms or offer pain relief medicines.
- Patients attending were generally fit and healthy. If any pain symptoms were identified patients were advised to seek support from their GP or midwife.

Patient outcomes

- Staff monitored the effectiveness of care and treatment. They used the findings to make improvements and achieved good outcomes for patients.
- The service did not participate in any local or national clinical audits or benchmark patient outcomes with any external organisations.
- Patient outcomes were measured through patient experience measures, such as patient feedback and complaints. Positive feedback from patients and low numbers of complaints indicated most patients had a positive experience.
- The service reported that there had been a total of 69 referrals made to NHS services between March 2018 and April 2019 as a result of unexpected findings during scan procedures. This included: -
 - Two patients had been referred to their GP for non-urgent findings on their scan.
 - Two referrals had been made to accident and emergency for ectopic pregnancy. Anectopic pregnancyis when a fertilised egg implants itself outside of the womb.
 - There had been four instances where staff directly liaised with NHS labour ward / assessment units so patients could be assessed immediately after their scan with the provider, following issues identified with third trimester pregnancies.
 - There had been 44 instances where patients who had miscarried were advised to contact their local early pregnancy assessment unit, including 27 instances where staff directly liaised with the units. The provider reported that they were not able to liaise with the early pregnancy units directly in other instances because of unavailability due to their opening times.
 - The service identified 17 abnormalities during scans that had not previously been identified and which needed further assessment. Staff liaised with the patient's local maternity unit or informed the patient discuss the findings with their midwife (if less than 20 weeks pregnant).



- The registered manager told us there were no instances where patients were readmitted for repeat scan procedures due to errors following their initial scan between March 2018 and April 2019.
- There was a process in place for peer review of scan reports to gain assurance that scan procedures were carried out in line with the service's policies. Each sonographer peer reviewed 10 randomly selected patient scan records from one of the other sonographers each month. The registered manager told us findings from peer reviews were discussed at monthly director's meetings to aid learning.
- The peer review audit for May 2019 showed there were no errors or concerns in relation to scans performed by the sonographers. The registered manger confirmed there had been no issues or concerns identified from peer reviewed reports between March 2018 and April 2019.

Competent staff

- The service made sure staff were competent for their roles. However, the service did not have processes in place for staff appraisal or supervision meetings to provide support and monitor the effectiveness of the service.
- Newly appointed staff underwent an induction process and competency assessment following the commencement of employment. Reception staff underwent a probationary period and this was approved following successful completion of competency assessments.
- We looked at the records for the four reception staff and found each had an up to date and complete competency assessment that was signed off by an approved trainer, such as the registered manager.
- The provider submitted evidence to show the sonographers had received competency based training as part of their substantive NHS roles and each sonographer maintained their individual competencies as part of their continual professional development (CPD).
- There was no formal process for appraisal or supervision of staff in the service. The sonographers underwent annual appraisal as part of their substantive NHS roles. The registered manager told us the individual sonographers held their appraisals individually and these were not routinely requested or reviewed as part of the service's assurance processes

- The receptionist we spoke with told us they did not have formal 1:1 discussions routinely or an annual appraisal.
 The receptionist confirmed they were able to discuss any personal or employment matters with their line manager whenever they needed to because of the small size of the service.
- All scan procedures were carried out by qualified sonographers and their qualification certificates were displayed in the reception area.
- Two of the sonographers were registered with the Health and Care Professions Council (HCPC). The third sonographer was also a qualified midwife and was registered with the Nursing and Midwifery Council (NMC). We saw evidence to show registrations with professional bodies were up to date.

Multidisciplinary working

- Staff worked together as a team to benefit patients. They supported each other to provide good care.
- There was effective daily communication and team working between the sonographers and reception staff so scan procedures could be coordinated and delivered effectively.
- Staff worked well with and routinely liaised with staff from other services (such as early pregnancy assessments units) so patients could be referred for further support if unexpected or significant findings were identified during ultrasound scans.

Seven-day services

- Diagnostic ultrasound scan services were available six days per week.
- Ultrasound scan procedures were available for patients six days per week. The service was open form 10am to 3pm on Wednesday but this was for administration purposes only and no patient appointments were made on Wednesdays.
- Scan procedures were available from 9am to 8pm on Monday, 9am to 7pm on Tuesday, 9am to 5pm from Thursday to Saturday and from 9am to 1pm on Sunday.

Health promotion

- Staff gave patients practical support and advice to lead healthier lives.
- Information leaflets and information on the provider's website provided some guidance for patients on managing their health during pregnancy.



- The registered manager also told us they signposted staff to local NHS services such as prenatal and antenatal classes.
- The provider reported that leaflets were available for patients based on count the kicks advice about their baby's movements during pregnancy.

Consent and Mental Capacity Act

- Staff supported patients to make informed decisions about their care and treatment. They followed national guidance to gain patients' consent.
- Staff understood how and when to assess whether a patient had the capacity to make decisions about their care.
- The service had a consent policy which outlined the process for obtaining implied, verbal and written consent from patients prior to undergoing scan procedures.
- The sonographers sought written consent from patients prior to undergoing scan procedures. Staff used specific consent forms depending on the type of scan to be undertaken, such as a dating scan consent form (to confirm pregnancy and confirm a heartbeat) and a consent form for routine and sexing scans. The consent forms clearly outlined the risks and benefits of the scan procedures to allow patients to make an informed decision.
- We looked at the consent forms for eight patients. They showed written consent had been obtained from patients and that planned scans were delivered with their agreement.
- The three sonographers had received mental health act training as part of their training within their NHS roles.
 The registered manager told us they would assess individual patients but patients with mental health conditions were unlikely to receive treatment at the service because the service did not carry out any procedures without signed consent from adult patients.
- The consent policy stated that if an adult patient lacked to the capacity to give or withhold consent to a scan, the service would not perform the examination and the patient would be advised to contact their GP or midwife.
- The service offered scan procedures for patients under 18 years of age. Consent for patients under 16 years of age was obtained through written parental consent and the registered manager told us patients were normally accompanied by their parent or legal guardian.

• The consent policy specified that patients aged 16 and 17 years were assessed to determine if they had the competency to receive treatment as an adult using the Gillick competence guidelines. However we did not see a specific consent form or assessment form in place in relation to this.

Are diagnostic imaging services caring?

Good



This is the first time we have rated this service. We rated caring as good.

Compassionate care

- Staff treated patients with compassion and kindness, respected their privacy and dignity, and took account of their individual needs.
- We saw that patients were treated with dignity, compassion and empathy. Staff spoke with patients in a friendly and polite way and we observed staff providing care in a respectful manner.
- During the scans we observed, women were treated sensitively and the sonographer was professional, respectful, and supportive at all times.
- We saw the privacy and dignity of patients attending the service was maintained and staff spoke discreetly with patients to maintain confidentiality.
- We spoke with four patients and two relatives of patients. They all said they thought staff were kind and caring and gave us positive feedback about ways in which staff showed them respect and ensured that their dignity was maintained. The comments received included: "staff friendly and helpful, happy with the service" and "brilliant service, more personal than a hospital".
- The provider did not gather formal patient feedback through satisfaction surveys. However we saw patient feedback comments on the provider's social media page and compliments and cards given to staff that showed patients were positive about the care and the treatment they received.

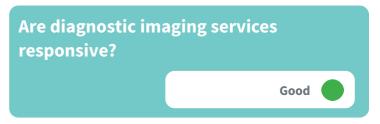
Emotional support



- Staff provided emotional support to patients, families and carers to minimise their distress. They understood patients' personal, cultural and religious needs.
- The staff we spoke with understood the importance of providing patients with emotional support. We observed the sonographer providing reassurance and comfort to patients during their scan.
- Patients told us the staff were calm, reassuring and supportive and helped them to relax prior to undergoing their scan procedure.
- The registered manager told us they supported patients where abnormalities or concerns were identified following a scan, including advising the patient to seek support from their general practitioner (GP) or midwife or making direct referrals to early pregnancy units where patients required urgent care and support.

Understanding and involvement of patients and those close to them

- Staff supported and involved patients, families and carers to understand their condition and make decisions about their care and treatment.
- Staff respected patients' rights to make choices about their care. We observed staff speaking with patients clearly in a way they could understand.
- Staff took into account individual patient preferences and fees were clearly explained to patients before scan procedures were undertaken.
- The patients we spoke with told us they were kept informed about their treatment. They told us the sonographers fully explained the scan procedure options to them and allowed them to make informed decisions. Patient comments included "staff clearly explained everything, consent process was clear" and "consent and fees were clearly explained".
- Patients' relatives of patients were encouraged to accompany patients during their scan. We saw that patient's relatives were involved and accompanied patients during the scan procedures we observed on the day of the inspection.
- There was a video-call service available so relatives or partners unable to accompany the patient (for example if they were or overseas) could view scan images.
- The service did not have a formal chaperone policy. However, the registered manager told us they would offer a chaperone if requested.



This is the first time we have rated this service. We rated responsive 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 service offered a range of ultrasound scan procedures for private fee paying pregnant adult patients and also for patients under 18 years of age.
- The service had a suitable environment for providing scan procedures to patients. There was sufficient capacity in the waiting area and the treatment room was spacious and provided a suitable and relaxed environment for patients to undergo scan procedures whilst maintaining their privacy and dignity.
- Patient appointments were booked in advance and this allowed staff to plan and deliver the scan procedures before patients attended their appointment.
- Ultrasound scan prices were clearly displayed on the service's website and on the patient consent forms. Staff clearly explained the costs and payment options to patients prior to undertaking scan procedures.
- The service offered a free bonding scan in association with the Cleft Lip and Palate Association (CLAPA), for babies that had been diagnosed with a cleft lip. This allowed parents to undertake a scan in a relaxing environment to help them form a closer bond with their baby before they are born. Records showed there were 27 CLAPA scans performed by the service between March 2018 and April 2019.
- The service did not charge a fee to patients for any pregnancies where no heartbeat was detected (such as miscarriage). The service also offered free scans for patients where their foetus had been diagnosed with a serious medical condition, such as serious heart defects or anencephaly (absence of a major portion of the brain, skull, and scalp).
- The service offered patients a range of baby keepsake and souvenir options, which could be purchased for an extra fee. This included additional images and soft toys.



 Patients could be seen multiple times throughout their pregnancy, and were offered a detailed report showing growth of their baby.

Meeting people's individual needs

- The service took account of patients' individual needs and preferences. However, not all staff had completed equality and diversity training and there was no information available for patients that were unable to speak English.
- Information leaflets about the services offered were readily available in the reception and waiting area.
 However, the leaflets we saw were only available in English.
- The provider's website also included a range of information for patients in relation to ultrasound scan procedures and supporting information relating to their pregnancy.
- The sonographers had received equality and diversity training as part of their NHS role but none of the receptionists had completed equality and diversity training and there was no equality and diversity policy in place. However, there was a competency assessment for reception staff that included aspects of equality and diversity.
- The service did not have access to an interpreter service for patients that were unable to speak English. The registered manager told us that patients self-referred and booked appointments for services so it was rare for a patient that was unable to speak English to attend the service. The registered manager told us staff would rely on those accompanying the patient to their appointment to act as an interpreter if the patient was unable to speak English. The use of relatives and/or friends as interpreters is discouraged and not considered best practice.
- We saw that children's toys were available in the waiting areas. These were routinely cleaned and maintained by staff and were available for patients that were accompanied by their children.
- The service was accessible for patients with limited mobility. The service was located on the ground floor of the premises and a portable ramp could be used to assist wheelchair access to the first floor.
- The service did not have a specific admission or exclusion criteria but patients that could not provide written consent were not admitted for scan procedures.

- Records showed the three sonographers had completed mental capacity and dementia awareness training. The registered manager told us it was rare for a patient living with dementia or a learning disability to attend the service and if they were to attend they would be accompanied by a carer during their scan procedure.
- The registered manager also told us if a patient with specific needs attended the service, they would make reasonable adjustments in order to accommodate the patient, such as offering appointments at the beginning or end of the day or encouraging the patient to visit the service prior to their appointment to help them familiarise with the service.

Access and flow

- People could access the service when they needed it and received the right care promptly.
- All patients attending the service were self-referred.
 Patients could book their appointments at a time and
 date of their choice in advance. Appointment bookings
 were made in person, by telephone or patients could
 directly book their appointment through the provider's
 website.
- Patients were given appointments based on their preference. There was no waiting list for appointments and patients could be seen promptly (including the same day in some instances).
- There was sufficient booking slots available for patients as the service operated six days per week and patients could book appointments in the evenings and on weekends.
- Patients were routinely given a 30-minute appointment slot but this could be extended if needed. The service followed the ALARA (as low as reasonably achievable) principles. This was in line with British Medical Ultrasound Society (BMUS) Guidelines for Professional Ultrasound Practice (December 2018). Ultrasound scans were completed within 15 minutes to help reduce ultrasound patient dose.
- We did not observe any issues in relation to admission and waiting times during the inspection. There was calm, relaxed environment and all patients on the day of the inspection were seen at their specified appointment time with minimal waiting upon arrival.
- The service reported there had been 40 scan procedure cancellations between March 2018 and April 2019. All



these were because the patient chose to cancel their appointment. There had been no cancellations attributed to the service, such as staffing or equipment issues, during this period.

 The service monitored patients that did not attend their appointments. There had been 204 instances where patients did not attend their appointments between March 2018 and April 2019. The registered manager told us patients that did not attend their appointment were not routinely followed up as the service provided was not clinically urgent and patients did not attend of their own choice.

Learning from complaints and concerns

- It was easy for people to give feedback and raise concerns about care received. The service treated concerns and complaints seriously, investigated them and shared lessons learned with all staff.
- Information describing how to raise complaints about the service were visibly displayed in the main reception and waiting area.
- Patients told us they were aware of how to raise a complaint. Staff we spoke with understood the process for receiving and handling complaints. One of the sonographers had a specific duty to manage complaint investigations and responses.
- The complaints policy stated that complaints would be acknowledged within two to five working days and investigated and responded to within five to seven days working days for routine complaints. This included the opportunity to discuss the complaint response with the complaints lead in a face to face meeting.
- Where patients were not satisfied with the response to their complaint, they were given information on how to escalate their concerns within the service and the complaint would be reviewed and responded to by a second sonographer.
- The service was not registered with an independent complaints adjudicator, such as Independent Sector Complaints Adjudication Service (ISCAS).
- The service received three complaints between March 2018 and April 2019. These were all for patients unhappy with the quality or outcome of the scan procedure.
- We looked at the records for the three complaints during the inspection. These showed that complaint investigations and response letters were completed appropriately. All three complaints were acknowledged

- and responded to in a prompt and timely manner. We saw evidence that duty of candour principles were applied verbally and in writing following complaints to the service.
- The registered manager told us that information about complaints was discussed during routine staff meetings to raise staff awareness and aid future learning. We saw evidence of this in the meeting minutes we looked at.

Are diagnostic imaging services well-led?

Requires improvement



This is the first time we have rated this service. We rated well-led as requires improvement.

Leadership

- Leaders had the integrity, skills and abilities to run the service. They understood and managed the priorities and issues the service faced. They were visible and approachable in the service for patients and staff.
- The service was managed by three directors, consisting
 of the registered manager (who was a sonographer) and
 two other sonographers. The sonographer on duty was
 responsible for the daily provision of care of treatment.
- The overall responsibility for overseeing the service was with the registered manager. The three sonographers also had specific responsibilities; for example the registered manager oversaw management of governance and risk and another sonographer acted as the quality manager with responsibility for managing audit processes and complaints.
- The reception staff had clear reporting structures in place. The receptionist we spoke with described the sonographers as approachable and supportive.

Vision and strategy

- The service had a vision for what it wanted to achieve and workable plans to turn it into action, which it developed with staff.
- The service had a set of six core values that were based on safety, quality, respect, customer satisfaction, exceeding expectations and integrity and honesty.
- There was also a code of conduct for sonographers document that included 11 statements and pledges



describing the commitment to providing high quality, patient-focused care by trained staff. The registered manager told us the code of conduct outlined the strategy for the service.

• The code of conduct and core values were visibly displayed in the main reception area and staff had a good understanding of these.

Culture

- Staff felt respected, supported and valued. They
 were focused on the needs of patients receiving
 care. The service promoted equality and diversity
 in daily work, and provided opportunities for
 career development. The service had an open
 culture where patients, their families and staff
 could raise concerns without fear.
- The registered manager and the receptionist we spoke with were highly motivated and positive about their work. They told us there was a friendly, patient-focused and open culture and that they received good support and regular feedback to aid future learning.
- The registered manager told us all the sonographers and reception staff worked well as a team. The three sonographers had worked together as a team since the service first opened in 2006. The four reception staff had also worked for the service over a long period, with length of employment within the service ranging from 18 months for the most recently appointed receptionist up to 10 years for the longest-serving receptionist. The registered manager told us long-term working relationships had helped to develop a positive culture within the service.
- There was guidance on how to raise issues or whistle blower concerns available in a staff handbook given to each member of staff working for the service.

Governance

- Leaders did not always operate effective governance processes throughout the service. We identified shortfalls in areas such as staff recruitment processes and the management of policies and procedures.
- The registered manager oversaw governance arrangements across the service. Governance information was discussed during monthly director's

- meetings that were attended by the three sonographers. Governance information was cascaded to reception staff through daily discussions and reception staff meeting that were held every three months.
- The service had clinical standard operating procedures that provided staff with guidance on conducting ultrasound scan procedures. These were all up to date and routinely reviewed and kept up to date.
- The service also had a range of organisational policies covering key processes such as quality assurance, recruitment, governance, risk assessments, safeguarding, health and safety, incident reporting and infection prevention and control.
- The registered manager told us these policies were routinely updated and staff were required to read and understand policies. However, we looked at 13 organisational policies and found that only two had documented review dates; the health and safety policy (reviewed May 2015) and the complaints policy (reviewed February 2019). The remaining policies did not have version control or specified review dates.
- The service did not have a fit and proper persons policy that all staff were required to comply with. We saw evidence that the registered manager underwent recruitment checks, such as enhanced disclosure and barring service (DBS) checks. However, the other two sonographers (directors) and the reception staff did not have up to date DBS checks in place.
- The registered manager reported following the inspection that DBS checks would be conducted for all existing staff and any new staff employed going forward.
- The recruitment policy outlined the recruitment checks to be carried out for reception staff prior to commencing employment, such as identification checks and references. We looked at the four staff files for the reception staff. These included information such as identification checks, contact details, curriculum vitae (CV's) and employment contracts. However, none of the reception staff files included any employee references.
- The registered manager told us the reception staff had been formally interviewed and offered employment but references had not been sought. The registered manager had completed a risk assessment that identified there was minimal risk to patients because the existing reception staff were long-term employees and had undergone a probationary period before they were offered permanent position.



 The service did not have statutory professional indemnity insurance arrangements, in accordance with British Medical Ultrasound Society (BMUS) guidelines. The registered manager told us they had an arrangement with an external organisation to provide legal assistance and support in the event of a claim being made against the service. There had been no legal claims made against the service between March 2018 and April 2019.

Managing risks, issues and performance

- Leaders used systems to manage performance effectively. However, they did not always identify and escalate relevant risks and issues or identify actions to reduce their impact.
- There was a risk assessment policy in place that outlined the process for identifying and managing risks to the service. Staff also used a risk assessment form to record key risks and mitigations and controls to manage individual risks.
- We saw that individual documented risk assessment forms were in place for reception staff training, slips and falls, fire safety, Control of Substances Hazardous to Health (COSHH) assessments, hand washing risks and bodily fluid spillage risks.
- The service did not have a list of completed risk assessments or a register of key risks. The registered manager told us key risks to the service were discussed at routine directors meetings.
- We saw evidence in meeting minutes that key risks
 relating to patient safety, staffing and equipment were
 discussed and managed through staff practice.
 However, not all risks to the service had been
 appropriately documented and mitigated. For example,
 we identified shortfalls in a number of processes during
 the inspection where risks had not been effectively
 managed. This included staff recruitment checks,
 monitoring of staff training requirements, management
 of policies and procedures and lack of professional
 indemnity insurance arrangements.
- We saw that routine audit and monitoring of key processes took place to monitor performance against patient safety standards and the provider's policies.
 Staff routinely carried out checks on infection control processes and safety checks on the ultrasound equipment.
- There was also a formal annual quality assurance audit that covered areas such as the suitability and

- cleanliness of the environment and equipment, accessibility, stock checks for consumable items, health and safety, emergency procedures and patient experience. The service achieved 100% compliance in all areas covered by the audit in the most recent audit (for December 2018).
- We identified shortfalls in the quality monitoring and assurance processes during the inspection. For example, there was no documented audit or monitoring in place to cover staff recruitment files, mandatory training compliance and overall governance processes and policies. This meant the registered manager could not be fully assured that all relevant processes were effective.

Managing information

- The service collected reliable data and analysed it.
 Staff could find the data they needed, in easily accessible formats, to understand performance, make decisions and improvements. The information systems were integrated and secure.
- There was no requirement within the service for staff to have completed data protection or information governance training. We saw evidence the sonographers had completed data protection training and information governance training as part of their training in their NHS organisations. One of the four receptionists had also completed data security training.
- The registered manager was accountable for data security within the service. There had been no data breaches reported by the service to the Information Commissioner's Office (ICO) between March 2018 and April 2019.
- Reception staff recorded patient appointments on an online electronic diary that was accessible remotely by all staff so they could identify in advance the number of patient appointments for a particular day.
- Patients were provided with a copy of the scan reports and images following their procedure. Scan reports were recorded and stored electronically. Paper based consent forms were also scanned electronically each day and paper copies were cross-shredded. This meant that staff could access all the information needed about the patient at any time.
- Electronic systems such as to manage patient appointments and store patient records required password access.



 Information such as audit records, incident reports, complaints records, equipment maintenance records and policies and procedures was securely stored in paper format and could be accessed by staff when needed. The registered manager told us they could access up to date national best practice guidelines when needed.

Engagement

- Leaders and staff actively and openly engaged with patients, staff, the public and local organisations to plan and manage services.
- Staff routinely engaged with patients during their scan procedures to gain feedback about the services. The registered manager showed us a selection of compliments, cards and letters that were complimentary about the service received by patients. We also saw patient feedback on the provider's social media platform was mostly positive.
- The registered manager told us patient feedback was regularly reviewed. Patient comments cards were available at the reception area and patients were encouraged to provide feedback about the service.
- The registered manager told us the service was mainly promoted through their website and through word of mouth from patients that had used the service. There was some engagement with the local community. For example, the service sponsored a local boys' football team and were involved in the 'Period Poverty' project where the service was a drop off point for sanitary wear for young girls.

• Staff engagement took place through daily communication and routine staff meetings. The receptionist told us they received good support and regular communication from the sonographers.

Learning, continuous improvement and innovation

- All staff were committed to continually learning and improving services.
- We saw evidence that information from incidents, complaints and feedback from patients was used to aid staff learning and look for improvements to services.
- The service had recently introduced a new on-line booking system which sent an email to the patients confirming details of their booking, including appointment details, procedure fees and if any preparation for the examination was needed.
- The service reported they planned to offer customers their images in a digital format and carried out a survey to obtain feedback from patients. Patient feedback showed the majority of patients preferred printed scan images and the service deferred the planned improvement as an area for future development.
- The registered manager told us the service was financially viable and sustainable because the sonographers and reception staff had worked effectively as a team for an extended period of time and their future plan was to focus on continuing to provide services for patients.

Outstanding practice and areas for improvement

Outstanding practice

- Staff clearly explained to patients verbally and in writing that the services offered were in addition to and not a substitute for their routine NHS pregnancy scans.
- The service offered a free bonding scan in association with the Cleft Lip and Palate Association (CLAPA), for

babies that had been diagnosed with a cleft lip. The service did not charge a fee to patients for any pregnancies where no heartbeat was detected and also offered free scans for patients where their foetus had been diagnosed with a serious medical condition. We identified this as outstanding practice.

Areas for improvement

Action the provider MUST take to improve

- The provider must take appropriate actions so that effective systems are put in place to identify training needs and monitoring of training compliance for all staff. Regulation 18 (1).
- The provider must take appropriate actions to ensure staff have access to regular supervision and appraisal. Regulation 18 (2)(a).
- The provider must take appropriate actions to ensure there are effective processes in place for governance, risk management and quality monitoring. Regulation 17 (1)(2)(a)(b)(d).
- The provider must take appropriate actions to ensure appropriate recruitment checks are undertaken for all staff in line with the fit and proper person's requirement. Regulation 19 (1)(2).

Action the provider SHOULD take to improve

- The provider should take appropriate actions so patients unable to speak English are appropriately supported.
- The provider should consider improving the arrangements for the management of spills from bodily fluids.
- The provider should consider improving the arrangements for the disposal of clinical waste.
- The provider should take appropriate actions to maintain documented records of risk assessments for each patient.

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 How the regulation was not being met The service did not have effective governance arrangements in place to ensure high standards of care were maintained at all times. Policies and procedures did not always include version controls or review dates. Risks had not been effectively managed in areas such as staff recruitment checks, monitoring of staff training requirements, management of policies and procedures and lack of professional indemnity insurance arrangements. There was no documented audit or monitoring in place
	to cover staff recruitment files, mandatory training compliance and overall governance processes and policies. This is a breach of Regulation 17 (1)(2)(a)(b)(d).

Regulated activity	Regulation
Diagnostic and screening procedures	 Regulation 18 HSCA (RA) Regulations 2014 Staffing How the regulation was not being met The service did not have an effective system in place to identify training needs and monitor compliance for all staff. The service did not have processes in place for staff appraisal or supervision meetings in order to provide support and monitor the effectiveness of the service. This is a breach of Regulation 18 (1)(2)(a)

This section is primarily information for the provider

Requirement notices

Regulated activity	Regulation
Diagnostic and screening procedures	Regulation 19 HSCA (RA) Regulations 2014 Fit and proper persons employed
	How the regulation was not being met
	Sufficient staff recruitment checks had not been carried out for all staff.
	This is a breach of Regulation 19 (1)(2)