CS Partners Medical Ltd - The Baby Scan Studio Colchester

Quality Report

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Date of inspection visit: 21 November 2019
Date of publication: 24/01/2020

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

Ratings

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

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

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

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

Summary of findings

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

Overall summary

CS Partners Medical Ltd The Baby Scan Studio Colchester is operated by CS Partners Medical Limited. The service provides diagnostic pregnancy ultrasound, gynaecological and fertility scans.

The service offers non-invasive prenatal testing (NIPTs) to self-funding women predominantly across Essex. NIPTs can be used to assess if a woman's foetus is at a higher risk of having certain genetic and chromosomal conditions, using a venous blood sample taken from the pregnant woman. It is referred to as non-invasive because it does not involve the insertion of a needle into the woman's abdomen or cervix, as is the case with more invasive testing, where cells are taken from the amniotic sac or placenta.

The registered manager also runs an ultrasound clinic in Marlow and another clinic at an independent hospital in Oxford. They work alongside a consultant to provide consultations and ultrasound scanning. The equipment is maintained by CS Partners Medical Limited.

The Marlow clinic (The Baby Scan Studio) provides diagnostic imaging for patients aged 18 years and over. It is registered with the Care Quality Commission (CQC) to provide the regulated activity of diagnostic and screening procedures. It has one ultrasound machine with one waiting area.

We inspected this service using our comprehensive inspection methodology. We carried out the announced part of the inspection on 21 November 2019. We gave staff four working days' notice that we were coming to inspect, to ensure the availability of the registered manager and clinics.

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 have not previously rated this service. At this inspection we rated it as **Good** overall.

- 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 assessed risks to patients, acted on them and kept good records.
- 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.
- Staff were caring, compassionate, kind and engaged well with patients and their families.
- Patients could access services and appointments in a way and a time that suited them.
- The manager promoted a positive culture that supported and valued staff. Staff reported their team worked well together and staff trusted and respected each other.

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

- The door at the back of the scanning room which gave access to a communal corridor to the staff kitchen and the toilets, was left unlocked when a patient was being scanned. This meant that the patient's privacy and dignity might not have been maintained at all times.
- The twice yearly team meetings were not formally minuted and therefore there was no evidence if actions were being followed up.

Summary of findings

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

Heidi Smoult

Deputy Chief Inspector of Hospitals - Central region

Summary of findings

Our judgements about each of the main services

Service	Rating	Summary of each main service
Diagnostic imaging	Good 	This is a diagnostic imaging service run by CS Partners Medical Ltd. The service is based in Colchester, Essex. We rated this service as good overall as it was good in safe, caring, responsive and the well led domains. We currently do not rate effective for this type of service.

Summary of findings

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Good

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Summary of this inspection

Background to CS Partners Medical Ltd - The Baby Scan Studio Colchester

CS Partners Medical Ltd The Baby Scan Studio Colchester is operated by CS Partners Medical Limited. The service has been registered with CQC since April 2011 and provides diagnostic pregnancy ultrasound services to self-funding women, who are more than six weeks pregnant and aged 18 years and above. All ultrasound scans performed at CS Partners Medical Ltd The Baby Scan Studio Colchester are in addition to those provided through the NHS for women who have chosen the NHS route of care.

The service also offers non-invasive prenatal testing (NIPTs), which is used to assess if a woman's foetus is at a higher risk of having certain genetic and chromosomal conditions, using a venous blood sample taken from the pregnant woman.

The service is registered with the CQC to undertake the regulated activity of diagnostic and screening procedures. The service has had a registered manager in post since April 2011.

The service did not use or store any medicines

Our inspection team

The team that inspected the service comprised a CQC lead inspector and one other CQC inspector. The inspection team was overseen by Fiona Allinson, Head of Hospital Inspection for East of England.

Why we carried out this inspection

We inspected this service using our comprehensive inspection methodology. We carried out the announced part of the inspection on 21 November 2019. We gave staff four working days' notice that we were coming to inspect, to ensure the availability of the registered manager and clinics.

Information about CS Partners Medical Ltd - The Baby Scan Studio Colchester

The service provides diagnostic imaging service (ultrasound scans) to self-funding patients predominantly across Essex. The service is situated on a single storey office building in business park with ample free parking spaces for patients and visitors.

CS Partners Medical Ltd The Baby Scan Studio Colchester offers many different scans and investigative tests including:

- Early pregnancy scans from six weeks gestation via the abdomen or trans-vaginal scan.
- 12 to 40-week reassurance scans which include growth measurements, fluid levels, a core doppler scan of the heart (after 26 weeks)
- 12-week nuchal scans with the blood tests to test for chromosomal abnormalities. A nuchal translucency scan is a screening test for Down's syndrome that involves measuring the fluid at the back of the foetus' neck (nuchal translucency) with an ultrasound scan.
- Gender scans at 16 weeks which include measurements of the baby, the position and general wellbeing.

Summary of this inspection

- 20-week anomaly scan for women who have chosen private healthcare for their entire pregnancy or in addition to their NHS scan.
- 4D scans between 28 to 32 weeks.
- Non-invasive prenatal testing (NIPTS)

During the inspection, we visited the service's location in Colchester, Essex. We spoke with three members of staff including the registered manager, one sonographer and a receptionist. We spoke with two women and reviewed six sets of records.

There were no special reviews or investigations of the service ongoing by the CQC at any time during the 12 months before this inspection. This was the service's first inspection using the next phase methodology.

Activity (January 2019 to October 2019)

- In the reporting period January 2019 to October 2019, there were 1338 ultrasound scans completed including 277 anomaly, 439 growth, 233 nuchal translucency, 54 bonding, 191 early pregnancy, 91 gender, 24 reassurances and 29 gynaecological scans. In the same period, they carried out 19 non-invasive prenatal tests.

Track record on safety

- No never events.
- No clinical incidents.
- No serious injuries.
- No incidences of hospital acquired Meticillin-resistant Staphylococcus aureus (MRSA), Meticillin-sensitive staphylococcus aureus (MSSA) hospital acquired Clostridium difficile (C.diff) or incidences of hospital acquired E-coli
- No complaint.

Services provided at the clinic under service level agreement:

- Non-invasive prenatal testing (NIPTS).
- Maintenance of medical equipment

Summary of this inspection

The five questions we ask about services and what we found

We always ask the following five questions of services.

Are services safe?

Good

Are services safe?

We rated it as **Good** because:

- The service provided mandatory training in key skills to all staff and made sure everyone completed it.
- Staff understood how to protect patients from abuse and the service worked well with other agencies to do so. Staff had training on how to recognise and report abuse, and they knew how to apply it.
- The 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.
- The design, maintenance and use of facilities, premises and equipment mostly kept people safe. Staff were trained to use them. Staff managed clinical waste well.
- Staff completed and updated risk assessments for each patient and removed or minimised risks.
- The service had enough staff with the right qualifications, skills, training and experience to keep patients safe from avoidable harm and to provide the right care and treatment.
- Staff kept detailed records of patients' care and treatment. Records were clear, up-to-date, stored securely and easily available to all staff providing care.
- The service managed patient safety incidents well. Staff recognised and reported incidents and near misses.

Are services effective?

We do not currently rate effective for this type of service, however we found:

- The service provided care and treatment based on national guidance and evidence-based practice. Managers checked to make sure staff followed guidance.
- Staff monitored the effectiveness of care and treatment. They used the findings to make improvements and achieved good outcomes for patients
- The service made sure staff were competent for their roles. The registered manager appraised staff's work performance.
- Staff worked together as a team to benefit patients. They supported each other to provide good care and communicated effectively with other agencies.

Summary of this inspection

- Staff supported patients to make informed decisions about their care and treatment. They followed national guidance to gain patients' consent.

Are services caring?

Good

We rated it as **Good** because:

- Staff treated patients with compassion and kindness, respected their privacy and dignity, and took account of their individual needs.
- Staff provided emotional support to patients, families and carers to minimise their distress. They understood patients' personal, cultural and religious needs.
- Staff supported and involved patients, families and carers to understand their condition and make decisions about their care and treatment.

Are services responsive?

Good

We rated it as **Good** because:

- The service planned and provided care in a way that met the needs of local people and the communities served. It also worked with others in the wider system and local organisations to plan care.
- The service was inclusive and took account of patients' individual needs and preferences. The service coordinated care with other services and providers.
- People could access the service when they needed it and received the right care promptly.
- 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. The service included patients in the investigation of their complaint.

Are services well-led?

Good

We rated it as **Good** because:

- 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 had a vision for what it wanted to achieve and a strategy to turn it into action. Leaders and staff understood and knew how to apply them and monitor progress.

Summary of this inspection

- Staff felt respected, supported and valued. They were focused on the needs of patients receiving care. The service had an open culture where patients, their families and staff could raise concerns without fear.
- The service had governance processes in place. Staff at all levels were clear about their roles and accountabilities and had regular opportunities to meet, discuss and learn from the performance of the service.
- Leaders and staff identified and escalated relevant risks and issues and identified actions to reduce their impact. They had plans to cope with unexpected events.
- 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.
- Leaders and staff actively and openly engaged with patients, and the public to plan and manage services.
- All staff were committed to continually learning and improving services. They had a good understanding of quality improvement methods and the skills to use them.

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	Good	Good
Overall	Good	N/A	Good	Good	Good	Good

Good

Diagnostic imaging

Safe	Good
Effective	
Caring	Good
Responsive	Good
Well-led	Good

Are diagnostic imaging services safe?

Good

We rated it as **good.**

Mandatory training

Staff had completed mandatory training in key skills.

Mandatory training for the reception staff included safeguarding vulnerable adults and children level 1 and 2, chaperone training and basic life support. We saw evidence that staff had completed the training and it was up to date.

The sonographers who worked for the service completed all their statutory and mandatory training in their substantive role within the NHS. The registered manager told us at the beginning of each year, sonographers were expected to provide their NHS mandatory training record. Evidence of this was submitted after the inspection. The mandatory training included infection prevention and control, information governance, fire safety, equality diversity and human rights, conflict resolution, safeguarding adults and children level 1 and 2, basic life support and the mental capacity act.

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 clear safeguarding processes and procedures in place for safeguarding vulnerable adults and children.

The policy set out responsibilities of staff and contact details of local authority referral. The policy also covered child sexual exploitation (CSE) and female genital mutilation (FGM).

At the time of our inspection, 100% of sonography and reception staff were compliant with adult and children's safeguarding training. Staff records showed all staff had completed the appropriate level of training in children's safeguarding training. This was in line with the Intercollegiate guidance 'Safeguarding children and young people: roles and competencies for health care staff (January 2019)' that states all staff who have contact with children should complete levels 1 and 2 children's safeguarding training.

The service had clear processes in place to raise concerns to the local authority safeguarding board.

Staff we spoke with during the inspection could describe how they would make a safeguarding referral and were aware of the situations when they would be required to do so.

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.

All the areas the service used were visibly clean and free from clutter.

Staff completed cleaning of all areas of the unit before the day's appointments started and at the end of the appointment list, this was recorded on a daily check sheet. We reviewed records which demonstrated that cleaning had taken place whenever the clinic was open.

Good

Diagnostic imaging

The scanning room floor had carpets which was not in keeping with Department of Health guidelines for clinical areas. We raised our concern with the registered manager who told us that this was already in the risk register and work was already underway to replace the carpet with a wipeable and washable surface. Following the inspection, the registered manager provided evidence that the floor had been replaced within eight working days from our visit.

The service had an up-to-date infection prevention and control policy in place, which set out staff responsibilities in relation to infection prevention, including hand hygiene.

The scanning room did not include a hand washing basin, but the kitchen and toilet were accessible next door which included appropriate hand washing facilities. The Department of Health's Health building note 00-003 clinical and clinical support spaces recommends an area where patients are having tests should have a clinical hand washing basin installed.

We saw hand sanitiser gel dispensers placed in prominent positions in the scanning room. We observed staff used the hand sanitiser appropriately.

Staff correctly cleaned and stored equipment such as probes used for intimate ultrasound investigations (for example, trans vaginal investigations). Staff covered the probes with an appropriate sheath during investigations and cleaned them with the recommended sporicidal wipes post ultrasound scan. This eliminated the risk of cross infection between patients. Personal protective equipment such as gloves were available when staff were taking blood samples for the non-invasive prenatal tests (NIPTs) tests.

The service had a blood spillage kit to ensure any blood spillages would be cleaned correctly and avoid any potential risk to patients and staff from blood borne viruses

We observed staff were compliant with hand hygiene and 'bare below the elbow' guidance, however they did not complete hand hygiene audits which would assure the service that staff were following the World Health's Organisations "five moments for hand hygiene" recommendations.

Environment and equipment

The design, maintenance and use of facilities, premises and equipment mostly kept people safe. Staff were trained to use them. Staff managed clinical waste well.

The Baby Scan Studio Colchester was situated in a single storey, brick-built business unit located on a business park.

The service was accessed by a single front entrance which leads to the waiting area with seating and a water-cooling machine. There was a toilet and staff kitchen accessed through the scanning room.

The scanning room could comfortably accommodate up to six people and included a scanning couch, chairs and a large screen for patients to view the images.

There was door at the rear of the scanning room, which led to a communal corridor giving access to the toilets and staff kitchen. During our inspection this door was not locked and there was a potentially risk where a patient's privacy and dignity may not have been maintained during a scan. The registered manager and sonographer told us the door would be locked when performing trans vaginal investigations.

Waste was handled and disposed of in a way that kept people safe. Staff used the correct system to handle and sort different types of waste and these were labelled appropriately.

Staff had correctly assembled sharps boxes to dispose of needles used for the NIPTs. An external company collected clinical waste bags and sharps boxes under a contract.

The service used one company for NIPTs which had their own packs and processes for labelling and sending the blood samples to the laboratory for analysis. The service tracked when these were sent.

The ultrasound machine was maintained and serviced annually We reviewed service records for the equipment, which detailed the maintenance history and service due dates. The last date of service for the machine was 15 May 2019 which meant it had been serviced within the last year.

Good

Diagnostic imaging

Due to the nature of the service they did not need resuscitation equipment however, they did have a first aid box. The contents of the first aid box were all in date.

Fire extinguishers were accessible, stored appropriately, and were all up to date with servicing. 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.

The service completed formal environmental risk assessments audits in areas such as water quality (Legionnaire's disease) and performed weekly fire alarm checks.

The service did not use any cleaning products required by Control of Substances Hazardous to Health (COSHH) regulations 2002 to be stored in a locked cupboard. Staff stored all cleaning products out of sight in the ultrasound room.

Assessing and responding to patient risk

Staff completed and updated risk assessments for each patient and removed or minimised risks.

The service had systems and processes in place to refer women to the local NHS trust or their GP if the scanning procedure indicated unexpected findings. The service referred women to the early pregnancy unit or the foetal medicine unit within the local NHS trust.

The service provided diagnostic reports following the baby scan and staff would advise women to take the report and the images to their NHS hospital, GP or midwife appointments.

Staff signposted women to the early pregnancy unit, GP, Midwife or other clinicians, if they reported symptoms such as vaginal bleeding or pain.

Due to the nature of service provided, there was no emergency resuscitation equipment on site. The service performed low risk baby ultrasound scans. In the event of a medical emergency or if a patient collapsed, staff called 999. In addition, the sonographers were trained in adult basic life support.

The registered manager reported they had not had any incidences where a patient requested frequent scans, but they did advise patients their scanning time was restricted to 10 -15 minutes as per the British medical ultrasound societies (BMUS) guidelines.

The service followed the 'as low as reasonably achievable' (ALARA) principles, outlined in the 'Guidelines for Professional Ultrasound Practice 2017' by the Society and College of Radiographers (SCOR) and BMUS. Details of this guidance was available for patients to read on the back of the registration form.

We saw the sonographer remind women on the NHS maternity care pathway about the importance of still attending their NHS scans and appointments. The sonographer made sure women understood the ultrasound scans they performed were in addition to the routine care they received as part of their NHS maternity pathway.

The service included current guidance on their website about the potential risks associated with all types of scans that were carried out at the clinic. Their website and terms and conditions stated clearly the 4D scans were in addition to the 12-week anomaly scans.

Staffing

The service had enough staff with the right qualifications, skills, training and experience to keep patients safe from avoidable harm and to provide the right care and treatment.

The service employed two sonographers and two receptionists on zero hours contract.

The registered manager owned the clinic, with two further directors that were not involved in the running of the business.

The service did not use bank or agency staff, since the two trained sonographers could cover each other's sickness or leave between them and there were no staff vacancies at the time of inspection. The registered manager was also a qualified sonographer and worked at the clinic when there was a need to cover sickness or annual leave.

The registered manager communicated updates and shift cover requirements using an online application. All staff we spoke with reported this worked very well.

Staff worked flexibly to ensure all ultrasound scanning appointments were staffed with a sonographer and a receptionist/chaperone. The service did not allow lone working and there were never less than two staff on duty.

Good

Diagnostic imaging

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.

Patients having ultrasound scans would receive a written report by the sonographer at the time of the scan. All NIPTs results were communicated to the patients via email or a phone call by the registered manager if the results were abnormal.

Staff saved the images on to a compact disc which they passed on to the patients for the obstetric scans. Images for other scans could be emailed to the patient to share with their GP's or consultants.

We reviewed six scan reports and six registration forms. Staff recorded information in a clear and correct way. This included the reason for the scan, the findings, and any recommendations if relevant.

The service kept completed records securely. Records were either stored securely on a password protected laptop or were locked in a filing cabinet in the scanning room. The ultrasound machine was also password protected restricting unauthorised access to patients' ultrasound pictures.

Staff removed records in the filing cabinet and shredded the records once a year. The reports on the laptop remained indefinitely to enable staff access to previous scan reports and use as a comparison with new ones. Article 5 (e) of the General Data Protection Regulation (GDPR) states personal data shall be kept for no longer than is necessary for the purposes for which it is being processed.

Medicines

The service did not store or administer any medicines.

Incidents

The service managed patient safety incidents well. Staff recognised and reported incidents and near misses.

The service had an up-to-date incident reporting policy and procedure in place to guide staff in the process of reporting incidents. Staff understood their responsibilities to raise concerns, to record safety incidents, and investigate and record near misses.

The service used a paper-based incident reporting system and had an accident book available in the clinic for staff to access. The registered manager was responsible for handling investigations into all incidents.

The adverse incident forms included a risk score on the impact and likelihood of the incident occurring again. However, from July 2018 to August 2019 the service had not reported on any adverse or serious incidents, therefore we were unable to review the completeness of the incident forms.

Staff we spoke with knew their responsibility to report incidents or near miss events and gave examples of the types of incidents they would report.

When things went wrong, staff apologised and gave patients honest information and suitable support. 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) when things go wrong with care and treatment, giving them reasonable support, truthful information and a written apology.

Providers of healthcare services must be open and honest with service users and other 'relevant persons' (people acting lawfully on behalf of service users)

Never events are serious largely preventable patient safety incident that should not occur if the available preventative measures have been implemented by healthcare providers. From July 2018 to August 2019, the service did not report any incidents classified as a never event taking place in their diagnostics services.

The registered manager was aware of the requirements for reporting incidents and sending notifications to the CQC and documented these in the service's risk management policy. However, at the time of inspection the registered manager had not been required to submit any notifications.

Good

Diagnostic imaging

Are diagnostic imaging services effective?

We do not currently rate effective in diagnostic imaging.

Evidence-based care and treatment

The service provided care and treatment based on national guidance and evidence-based practice. Managers checked to make sure staff followed guidance.

Sonographers followed national guidelines such as from the British Medical Ultrasound Society (BMUS) and the Society of Radiographers (SCoR). Staff also followed NHS foetal anomaly screening programme (FASP) guidelines when completing diagnostic ultrasound scan procedures.

The service had protocols to ensure they offered patients the right ultrasound scans or diagnostic tests to meet their specific needs. We reviewed the protocols which all referenced national guidance such as the Royal College of Radiographers (RCR) and British Medical Ultrasound Society (BMUS).

We reviewed seven policies, procedures and protocols which were version controlled and current. The polices referred to current legislation, local and national guidelines and best practice guidance, including National Institute for Health and Care Excellence (NICE), Royal College of Radiologists (RCR), Royal College of Obstetrics and Gynaecology (RCOG), British Medical Ultrasound Society (BMUS) and Society of Radiographers (SoR).

All staff we spoke with were aware of the policies, content and where to find them.

The service followed as low as reasonably achievable (ALARA) principles outlined by the Society and College of Radiographers. Sonographers did not scan for longer than 20 minutes and would not repeat scans within seven days of the earlier scan, which reduced any risks that prolonged scans may cause to the unborn baby.

The registered manager updated the protocols based on those used at the local NHS trust. There were protocols for non-invasive prenatal tests (NIPTs) provided by the suppliers of the blood sampling packs and protocols based on best practice guidance for foetal anomaly.

Nutrition and hydration

Due to the nature of service provided, food and drink were not required or provided. However, patients and visitors had access to a water cooler in the waiting room.

Staff gave women information on drinking water before a scan to ensure they attended with a full bladder which enabled the sonographer to gain a better view of the unborn baby.

Pain relief

Staff did not formally check pain levels as the procedure was pain free. However, we saw that staff asked patients if they were comfortable during their scan.

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 had an audit programme to assure itself of the quality and safety of the clinic. For example, the registered manager reviewed six randomly picked ultrasound scans from each sonographer and the reports for each sonographer on a quarterly basis. The register manager emailed each sonographer with the results and to discuss any improvements which may have been required in both the reporting and image quality.

Staff reported this was a good process and helped them to identify areas of improvement in both the image quality and report writing. We saw the July 2019 audit. The image and report from were mostly of good quality and those that did not meet the standards, the registered manager highlighted and addressed the issue with the individual sonographer.

The service used audits to continually improve patient services. For example, the service completed a waiting times audit which highlighted patients did not know they needed to arrive five minutes earlier to complete a registration form. The pre-appointment information email was updated to reflect this information. Further audits completed included the length of time spent on telephone calls and the subjects discussed.

When sonographers identified any unusual or abnormal images that needed further referral to NHS or non-NHS

specialists, where appropriate, they followed up the outcomes to both offer support and to assess the accuracy of the diagnoses through a phone call or email communication.

The service sought feedback from patients on the outcomes of their scans, and we saw this feedback indicated patients were satisfied with the results due to the high level of positive responses.

The registered manager told us there were no instances where patients were rescanned due to errors following their initial scan between July 2018 and August 2019.

Competent staff

The service made sure staff were competent for their roles. The registered manager appraised staff's work performance.

All sonographers working at the clinic were employed in substantive NHS posts and therefore received appraisals there. These were kept as part of their personnel file by the registered manager.

The two-reception staff had been appraised by the registered manager in the last 12 months. An appraisal is an opportunity for staff to discuss areas of improvement and development within their role in a formal manner. We saw evidence of this in the appraisal paperwork and staff also reported development needs discussions took place whenever required, either formally, or informally. We saw evidence of the registered manager's appraisal from July 2019.It detailed a review of ultrasound scans and reports which were very positive and the personal development the registered manager had undertaken.

All sonographers working within the service were registered with the Health and Care Professional's Council (HCPC) and on the voluntary register with the Society of Radiographers.

The service had an induction pack for staff, which included local information such as health and safety, fire drill and infection prevention and control. The registered manager supervised new staff until they felt confident in their role. The receptionists had a list of duties they were expected to complete for each clinic session and the registered manager reported they would review that these were completed each day.

Multidisciplinary working

Staff worked together as a team to benefit patients. They supported each other to provide good care and communicated effectively with other agencies.

There was effective daily communication and team working between the sonographers and reception staff so scan procedures were coordinated and delivered effectively.

Staff reported they all worked well together, and communication was positive. During inspection we observed positive communication between the registered manager, the receptionist and the sonographer.

The registered manager and sonographers worked closely with healthcare professionals in the NHS, including early pregnancy assessment units, foetal medicine and GPs to provide a seamless treatment pathway. The service contacted the relevant foetal medicine unit at the local NHS trust directly if they identified a patient who was discovered to have, for example, an anomaly, or an ectopic pregnancy.

The service liaised effectively with the non-invasive prenatal tests (NIPT) equipment providers, to ensure results were communicated within the three to five day expected window to patients.

Seven-day services

The service did not open every day however, staff worked to provide appointment flexibility to accommodate the needs of patients.

The service ran clinic sessions designed to accommodate the needs of patients and their families. For example, evening and weekend appointments enabled patients to attend with their family, partners and children.

Health promotion

The service provided families with information leaflets about the non-invasive pre-natal testing (NIPTs) and nuchal scanning. The sonographer would refer the women back to their NHS or private midwife, GP or trust if they had specific questions or concerns relating to their pregnancy or ultrasound scan result.

Consent and Mental Capacity Act

Good

Diagnostic imaging

Staff supported patients to make informed decisions about their care and treatment. They followed national guidance to gain patients' consent.

We reviewed six consent records which demonstrated that written documented consent was obtained prior to scan.

All patients received written information to read and sign before their scan. This included a consent form, terms and conditions including the 4D scan not being a replacement for the NHS anomaly scan.

All staff were aware of the importance of gaining consent from patients before conducting an ultrasound scan. The sonographer confirmed names, spellings and dates of birth prior to the scan and obtained verbal consent to begin.

Staff understood their responsibility to gain consent from patients attending the clinic for ultrasound scanning services. The registered manager explained the procedure and patients had the opportunity to withdraw if they wished. The sonographers always confirmed with patients what they wanted from the scan, the limitations of the scan and how long the procedure would take.

The registered manager and sonographers completed training in relation to the Mental Capacity Act 2005 which formed part of their NHS mandatory training.

The registered manager told us that there had never been an instance where a patient attended who had lacked the capacity to consent.

Are diagnostic imaging services caring?

Good

We rated it as **good.**

Compassionate care

Staff treated patients with compassion and kindness, respected their privacy and dignity, and took account of their individual needs.

During the inspection, we saw that staff greeted patients and relatives in a warm and friendly manner, introducing themselves by name.

The service carried out their own feedback survey and received consistently positive praise. A review of the feedback showed patients were positive about their experience at the service and also indicated that patients had returned to the service for further scans at later stages in their pregnancy.

The feedback we reviewed also described staff as 'wonderful, friendly, helpful, kind and caring'. We also noted the vast majority of feedback was positive about the speed of access to the scan and the personalised service that was offered.

The two patients we spoke with during the inspection told us that the service was recommended to them by others and that they had used it more than once. Both patients had had the clinic recommended to them and would be happy to recommend the clinic to their friends and family.

Patients were able to give feedback through feedback forms in the clinic, an email to the service, or via open social media platforms.

Emotional support

Staff provided emotional support to patients, families and carers to minimise their distress. They understood patients' personal, cultural and religious needs.

During our inspection we observed two scans. Throughout these scans the sonographer described what they saw and explained findings in a way the patient could understand. For example, we saw the sonographer measuring each part of the baby and clarifying their findings to reassure the patient.

The patients we spoke with told us staff were professional and supported them well. They considered their privacy and dignity had been maintained throughout their time in the unit.

The service allowed family members to accompany women during their scans.

Staff recognised that providing emotional support to women was an important part of their role. Staff described how they explained distressing findings, to help people understand the scan report and know what to do next. The service did not provide links to counselling services, but recommended patients speak

with the health professionals involved in their care. For example, if a woman had concerns about foetal movements, staff advised to liaise with their midwife or GP for further guidance and reassurance.

The sonographer saw patients back in the scanning room to discuss the report and relevant pictures, or DVD's in private. This also enabled patients who had received bad news privacy to absorb the information and ask further questions.

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 actively included women and those close to them to be involved in the scanning process. Women told us that staff provided care to them and involved those close to them.

During our inspection we saw patients and their families treated with kindness and respect by staff. Staff welcomed patients and their families including children and there was enough room to accommodate five guests with the patient, in the clinic room. This especially helped children to bond with their unborn sibling.

Staff took time to explain the procedure before and during the scan. We saw the sonographer fully explain what was going to happen throughout the scan. They used appropriate language to explain the position of the unborn baby and the images on the monitors. They asked patients if they had any questions throughout and at the end of the scan.

The sonographer explained the findings and if appropriate gave the patient the report from the scan, photos and a compact disc. All patients we spoke with after the appointment reported to have been very well informed of the ultrasound findings and their next steps to take.

The service's website provided clear information around the costs of ultrasound scanning and non-invasive prenatal testing. When patients arrived in the clinic, receptionists reviewed the prices of the scans with the patients to ensure they had booked the correct scan for their requirements and were aware of the charges.

Are diagnostic imaging services responsive?

Good

We rated it as **good.**

Service delivery to meet the needs of local people

The service planned and provided care in a way that met the needs of local people and the communities served. It also worked with others in the wider system and local organisations to plan care.

The clinic was in a single storey, brick built business unit located on a business park on which housed the ultrasound scanning clinic and a waiting area. There was clear signage on the premises, there was free car parking on site and the unit was on a bus route.

The facilities and premises mostly met the needs of patients and their families, including children, that accompanied the patients to their scan. However the waiting area did not have toys or books to keep the children occupied.

The patients we spoke with said the clinic was easy to find, and provided a calm, professional environment. There was a comfortable waiting room, with magazines and a water cooler. The waiting room was separate from the scanning room, which helped promote privacy. Separate from the waiting room on the same floor was a toilet for patients and staff and a staff kitchen which was accessed through the scanning room. All areas of the service were accessible to wheelchair users.

At the time of our inspection the service only provided private ultrasound scans and did not complete any imaging on behalf of the NHS or other private providers. The service had a range of packages with different price options which were clearly displayed on the website. Patients could book appointments online, over the phone or be referred by a health care professional. The service offered out of hours appointment times, in the evenings and on Saturdays.

Good

Diagnostic imaging

Reception staff discussed the ultrasound packages with the patients upon entering the clinic to ensure the package met the patient's needs. All obstetric packages included a wellbeing scan.

Meeting people's individual needs

The service was inclusive and took account of patients' individual needs and preferences. The service coordinated care with other services and providers.

The service was accessible to all individuals. All areas of the service were accessible to wheelchair users.

Patients book appointments online or by telephone at a time to suit them.

The service's website included a range of information for patients in relation to ultrasound scan procedures and supporting information relating to pregnancy.

Patients we spoke with reported their appointment times were long enough for them to ask questions and gain reassurance. The registered manager reported half an hour was allocated to each appointment slot to ensure patients had time to complete their questionnaires and for the sonographer to complete the report. It also allowed time for the woman undergoing obstetric scans to go for a walk to encourage the foetus to move to improve the scan image.

Staff told us that the registered manager was always available via telephone, if there were any patient or staff concerns, for advice or in the event of an adverse incident.

Access and flow

People could access the service when they needed it and received the right care promptly.

Access to the service was on a self-referral basis only. Appointments for early reassurance, gender, growth and wellbeing and 4D scanning packages were offered in a timely manner.

The service did not have a waiting list for ultrasound appointments. Patients could self-refer to the service on the same day, particularly for obstetric viability appointments. Patients could book their scans through the website, via telephone or email.

Booking was managed by the administration team in the head office. Therefore, booking requests or queries were managed centrally whilst the clinic was closed, which meant there was someone available to answer patients' questions and book appointments.

The sonographer gave the results of the ultrasound scans to the patients immediately after the scan which enabled them to discuss their results with the relevant health care professional in a timely manner.

On the day of inspection, we saw patients arrive in the reception area and wait no longer than five minutes for their scan. The reception audit showed the longest a patient had to wait for an appointment during August 2019 to October 2019 was 30 minutes which happened once. Because of the audit, the service had made changes to the information letter sent when patients booked their appointment which advised them to arrive five minutes early to complete the registration form.

The booking system was flexible and allowed changes to packages to meet patients' choices. Patients paid a small deposit upon booking the scan and could change the package when they attended for their scan appointment if they wished.

The service performed 1338 scans from January 2019 to October 2019. These scans included 277 anomaly, 439 growth, 233 nuchal translucency, 54 bonding, 191 early pregnancy, 91 gender scans, 24 reassurances and 29 gynaecological scans. For the same period, they carried out 19 non-invasive prenatal tests.

From July 2018 to August 2019 the service had not cancelled any scans.

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.

The service had an up to date policy for managing complaints, which included timescales for acknowledging a complaint (three working days) and investigated and responded within 10 working days.

Good

Diagnostic imaging

There was information on the service's website on how to make a complaint, and there was a comments and compliments box in the waiting area for patients to give feedback on the service.

Patients we spoke with during the inspection saw no reasons to make a complaint and could not suggest any improvements the service could make.

The service received no written complaints from July 2018 to August 2019.

CQC had not received any complaints about the service in the last 12 months prior to the inspection

The registered manager told us that information about any complaints received would have been shared with staff through the electronic application or face to face and would discuss in the twice a year team meetings.

Are diagnostic imaging services well-led?

Good

We rated it as **good.**

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.

CS Medical Partners Limited was owned and run by the registered manager who took responsibility for all aspects of the service, including governance, clinical management, health and safety and quality. The service had three other directors who were financial investors and were not directly involved in the daily running of the business.

Staff told us the registered manager was accessible and approachable. The registered manager kept staff informed of any developments for the service.

Staff told us the registered manager had the skills and experience to appreciate the roles they completed and offered valuable support.

Vision and strategy

The service had a vision for what it wanted to achieve and a strategy to turn it into action. Leaders and staff understood and knew how to apply them and monitor progress.

The service's vision was to provide accurate, detailed and diagnostically correct information to patients, whatever the type of scan they have attended for.

The registered manager was able to identify areas of development for the service and had a strategy in place to meet these requirements. For example, until August 2019, the service had a contract with a local private midwifery provider to provide all their ultrasound scanning. This meant that the service had full day bookings dedicated to the midwifery service. Despite losing this contract without any notice, the service has managed to continue to provide a viable business and service from the Colchester site.

Staff we spoke with were aware of the direction of the service and any developments or changes were communicated by the registered manager.

Culture

Staff felt respected, supported and valued. They were focused on the needs of patients receiving care. The service had an open culture where patients, their families and staff could raise concerns without fear.

Staff told us they worked together well as a team and there was an open and honest culture. The registered manager addressed performance issues through open and honest, one to one feedback with staff.

All staff spoke proudly about their roles within the service and staff felt supported in their work. Staff told us they felt valued and supported by colleagues and the registered manager.

There was a strong emphasis on the care of patients and their families. Staff promoted openness and honesty and understood how to apply the duty of candour.

We saw the registered manager effectively engage with staff. All staff we spoke with told us the registered manager was supportive accessible and visible.

Good

Diagnostic imaging

Following the inspection at another location, the registered manager responded positively to feedback. The improvements were made and implemented at both locations following feedback. This showed a culture of openness and willingness to learn and improve.

Governance

The service had governance processes in place. Staff at all levels were clear about their roles and accountabilities and had regular opportunities to meet, discuss and learn from the performance of the service.

The service had systems and processes to support the delivery of a safe and caring service.

The registered manager oversaw and made sole decisions about all governance arrangements across the service. Governance information was cascaded to the staff through use of an electronic application and at the twice-yearly staff meetings as well as informally daily.

The service improved service quality through regular audits and clinical reviews by the registered manager. Governance arrangements were clear and appropriate to the size of the service.

The registered manager reviewed results of audits, feedback from patients and other stakeholders quarterly including any incidents or complaints and any new legislation relating to the clinic.

Staff understood their roles and only carried out scans and procedures in line with their competencies.

Information shared with team members via the electronic application included general service updates, incident and complaint outcomes and cover arrangements for the service. However, the twice yearly team meetings were not formally minuted. The registered manager provided their informal notes from the meeting held in January 2019. This did not provide assurance team members who missed the meeting were fully informed of the service's changes and performance. However, the registered manager reported all staff attended these meetings.

Managing risks, issues and performance

Leaders and staff identified and escalated relevant risks and issues and identified actions to reduce their impact. They had plans to cope with unexpected events.

The registered manager understood the risks relating to the premises, service delivery and business. There was evidence that risks had been identified and mitigated and these were formally recorded within a risk management framework. For example, a risk document included the carpets in the scanning room needing to be replaced and this was documented on the risk register including the impact, dates the risks were added and dates of next review.

The service identified, and documented risks associated with the environment and had health and safety audits including fire and legionnaires audits. The service had public liability insurance and staff were covered by medical indemnity.

To mitigate the risks of lone working, there were always at least two staff on site when the service was open.

The audit program undertaken by the registered manager helped them to identify any risks to the provision of a quality service rating to performance and adherence with policies and guidance.

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 service was registered with the Information Commissioners Office (ICO) and detailed this on their website. They were also compliant with the Payment Card Industry Data Security Standard (PCIDSS) which every business taking card payments is required to have. It includes a yearly PCI DSS compliance assessment to ensure the service protects cardholder data to the highest standard.

Patients consented for the service to store their records. This was part of their signed agreement within the form detailing the ultrasound process. This showed the service's compliance with the General Data Protection Regulation (GDPR) 2018.

Good

Diagnostic imaging

The service had an up to date privacy notice policy which referred to all relevant legislation regarding staff responsibilities, documentation standards and the retention of records.

There was enough information technology equipment for staff to work with across the service. This meant staff had access to the required information at the time they needed it.

The service had not experienced any information breaches.

Engagement

Leaders and staff actively and openly engaged with patients, and the public to plan and manage services.

The service welcomed feedback from patients and visitors through a variety of methods including the service's website and a variety of social media platforms. In addition, patients and their families could fill in a comment card whilst they were waiting for their scan.

The Baby Scan studio had received high levels of satisfaction ratings from their users. Feedback we reviewed (13 comments) were very complimentary. We also reviewed 10 comments from the comments box in the reception area, where each patient had spoken very highly of the service.

The service had a system and process in place to refer patients to NHS services and other health providers. The registered manager and the sonographers told us that they had a good relationship with the local NHS trust.

Staff told us that the registered manager consistently sought feedback from all staff members with regards to improving the safety and quality of the service and staff felt their ideas were listened to. Staff we spoke with appreciated the twice a year social events to bring the team together.

Learning, continuous improvement and innovation

All staff were committed to continually learning and improving services. They had a good understanding of quality improvement methods and the skills to use them.

Staff took pride in their work and aimed to make improvements where possible. The registered manager said they shared learning from the sonographers working in the NHS trusts and found this useful.

Outstanding practice and areas for improvement

Areas for improvement

Action the provider SHOULD take to improve

- The provider should consider formal minuted team meetings to share feedback to all staff.
- The provider should consider installing a hand wash basin within the ultrasound room.
- The provider should consider having access to interpreting services.