Peek a Baby

Quality Report

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

Ratings

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

Summary of findings

Letter from the Chief Inspector of Hospitals

Peek-A-Baby is operated by Ultrasound-Care Scanning Services Ltd and provide clinical and diagnostic scans, and baby ultra sound scans, including 2D and 4D images and videos. The baby scanning is provided under the Peek-A-Baby brand name and makes up 95% of the business. It provides women who use their service with images for keepsakes and diagnostics for reassurance. Other clinical and diagnostic scans are provided under the providers Ultrasound-Care Scanning Services division and provide scans for men and women over 18 years of age.

We inspected this service using our comprehensive inspection methodology. We undertook an announced inspection on 26 February and conducted a telephone interview on 24 March 2020. To get to the heart of patients' experiences of care and treatment, we ask the same five questions of all services: are they safe, effective, caring, responsive to people's needs, and well-led? Where we have a legal duty to do so we rate services' performance against each key question as outstanding, good, requires improvement or inadequate.

Throughout the inspection, we took account of what people told us and how the provider understood and complied with the Mental Capacity Act 2005.

We rated it as **Requires improvement** overall

Our key findings were as follows:

- The service did not have access to an identified level three safeguarding trained lead. This was not in line with national guidance.
- The service did not routinely time patient scans and did not record those which exceeded 15 minutes.
- The service had some arrangements in place to assess and manage risks to patients, however the process for risk assessing individual patients was not sufficiently robust.
- There was no formal risk register for the risks the service had identified.
- The service used family members to translate for patients who did not speak or understand English.
- The service did not keep records of team meetings and minutes and actions were not recorded.
- Actions following complaints were not recorded and there was no formal log of all complaints.
- There were gaps in the delivery, recording and implementation of quality monitoring.The service did not have a documented business continuity plan.
- The service did monitor or analyse patient feedback.

However, we also found the following areas of good practice

- Managers in the service monitored staff compliance with mandatory training in key skills and made sure everyone had completed training specific to their roles to support the delivery of safe care.
- Staff understood safeguarding processes and were confident to escalate concerns.
- The maintenance and use of equipment kept people safe.
- Where possible, complaints were resolved at the time they were made, and free rescans were offered if the scan could not be completed.
- The service had enough staff with the right qualifications, skills, and training to provide the right care and treatment. Employment and qualification checks were carried out on all staff.
- Peoples' individual care records were completed and managed in a way that kept people safe.
- The service provided care and treatment that was based on national guidance and evidence of its effectiveness.
- Throughout our inspection we saw that patients were treated with compassion, kindness, dignity, and respect. People could access the service when they needed it. Waiting times from referral to treatment were in line with good practice.
- Leaders of the service had the right skills and experience to run the service.

Summary of findings

- The managers across the service promoted a positive culture that supported and valued staff, creating a sense of common purpose based on shared values.
- The service managed and used information to support its activities, using secure electronic systems with security safeguards.

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	Requires improvement 	Overall, the care provided by the service was requires improvement for safe, responsive and well led. Caring was rated as good. We do not rate effective in outpatient settings. There was no access to a level three safeguarding lead. There were gaps in the delivery, recording and implementation of quality monitoring. There was no risk register for the service. Ultrasound scans were not timed. The service did monitor or analyse patient feedback Complaints were investigated however actions were not recorded following complaints. The service did not document their team meetings. There was no formal translation service in place, and the provider had been using family members where this was required. The service did not have a documented business continuity plan There was no evidence of audits undertaken to monitor or improve infection prevention and control. The service had some arrangements in place to assess and manage risks to patients, however the process for risk assessing individual patients was not sufficiently robust. However: The service had enough staff to provide the service and keep patients safe. Staff had training in key skills, understood how to protect patients from abuse, and managed safety well. Where possible, complaints were resolved at the time they were made, and free rescans were offered if the scan could not be completed. Staff took account of patients' individual needs and helped them understand their conditions. Patients were happy with the care they received, and we found the service to be caring and compassionate.

Summary of findings

Scans were reported on during the procedure and were available immediately.

Summary of findings

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Peek a Baby

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Diagnostic imaging

Summary of this inspection

Background to Peek a Baby

Peek-A-Baby is operated by Ultrasound-Care Scanning Services Ltd. The service opened in 2017. It is a private service in Birmingham, West Midlands. The service primarily serves the communities of Birmingham. It also accepts patients from outside this area. The provider also operates the same type of service from a second location.

Peek- A-Baby began as a non-clinical non-diagnostic scanning studio providing keepsake scans in 2D and 4D with the health and wellbeing of both mother and baby at the forefront of their objectives. The service has now evolved to offer women diagnostic ultrasounds for reassurance in early pregnancy, growth scans and anomaly scans. It also offers other types of scan to men and women. This includes for example, abdominal scans, prostate, kidney and bladder scans, aortic surveillance scans and fertility scans

To accommodate the diagnostic scanning, Ultrasound-Care Scanning Services Ltd was formed and the service expanded to include a second scanning room and waiting area. Facilities include two consultation rooms, two waiting areas and one reception area.

The service has had a registered manager in post since it opened.

Our inspection team

The team that inspected the service comprised of two CQC lead inspectors. The inspection was overseen by Fiona Allinson, Head of Hospital Inspection.

Information about Peek a Baby

The service provides diagnostic imaging and is registered to provide the following regulated activities:

- Diagnostic and screening procedures.

During the inspection, we visited the service for one day, and carried out telephone interviews on 24 March 2020. We spoke with six staff including the provider. We spoke with three patients and we observed one scan procedure.

During our inspection we reviewed six sets of patient records.

The baby scanning service provided mainly mementos, early pregnancy scans and baby gender scans. Diagnostic scans carried out by the service included for example, abdominal scans, bladder, bowel and kidney scans and aortic valve scans. Patients were provided with a written report during their appointment which could be taken to the patients GP, or other healthcare provider for further investigations or treatment, should this be necessary.

The service usually operated seven days per week with morning and evening surgeries. The clinic was closed on Monday mornings.

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 had not been previously been inspected.

In the reporting period August 2018 to August 2019 the service carried out 7000 baby scans, and approximately 200 other diagnostic scans.

All baby scans were privately funded.

From August 2018 to August 2019

There were no never events.

There were no incidents.

There were no serious injuries.

There were nine complaints, including one formal complaint.

Summary of this inspection

There were no healthcare associated infections.

Services provided at the service under service level agreement:

Maintenance of medical equipment

Clinical waste and refuse collection

Maintenance of fire safety equipment

Portable electrical appliance testing.

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?

Requires improvement

We rated it as **Requires improvement** because:

- The service did not have access to a level three trained safeguarding lead.
- There was no evidence of audits undertaken to monitor or improve infection prevention and control.
- The service did not complete comprehensive individual risk assessments.

However, we also found the following areas of good practice

- The service monitored staff compliance with mandatory training in key skills 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 had enough staff with the right qualifications, skills, training and experience to provide the right care and treatment.
- Peoples individual care records were completed and managed in a way that kept people safe. Records were clear, up-to-date, and easily accessible to staff providing ultrasound scans.

Are services effective?

We 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.
- The service monitored patient outcomes
- Staff had the right qualifications, skills, knowledge and experience to do their jobs.
- Staff of different disciplines worked together as a team to benefit women and their families.
- Staff understood the requirements of the Mental Capacity Act when making decisions about patient's ability to consent to treatment. Staff understood how and when to assess whether a woman had the capacity to make decisions about their chosen care.

Are services caring?

Good

We rated it as **Good because:**

We found the following areas of good practice:

Summary of this inspection

- Staff cared for patients with compassion.
- 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.

However, we also found that:

- The service did monitor or analyse patient feedback

Are services responsive?

Requires improvement

We rated it as **Requires improvement** because:

- Although the provider had access to an online translation application, family members were sometimes used to translate for patients who did not speak or understand English.
- The response to complaints were not documented and themes were not identified and shared in order to enable the service to improve.
- However, we also found the following areas of good practice;
- The service delivered services in a way that met the needs of patients.
- People could access the service when they needed it. Waiting times were minimal and most patients could get an appointment as soon as they required one.
- Where possible, complaints were resolved at the time they were made, and free rescans were offered if the scan could not be completed.

Are services well-led?

Requires improvement

We rated it as **Requires improvement** because:

- Although staff said they held regular team meetings, these were not formally recorded, and there were no minutes available.
- The service had a vision for what it wanted to achieve, however they were working towards producing a written strategy.
- There was limited engagement with the public to plan and manage appropriate services
- There were some gaps in the delivery, recording and implementation of quality monitoring.

However, we found the following areas of good practice:

- Leaders of the service mostly had the right skills and experience to run the service.
- The managers promoted a positive culture that supported and valued staff, creating a sense of common purpose based on shared values.

Detailed findings from this inspection

Overview of ratings

Our ratings for this location are:

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

Requires improvement

Diagnostic imaging

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

Are diagnostic imaging services safe?

Requires improvement

We rated it as **requires improvement.**

Mandatory training

The service provided mandatory training in key skills to all staff and made sure everyone completed it.

Staff had completed their mandatory through a recognised on-line training programme for healthcare staff. Training included, basic life support, equality, diversity and human rights, safeguarding children and adults, information governance, conflict resolution, complaints handling, health and safety, fire safety, infection prevention and control and manual handling.

Staff said the training was appropriate to their needs. All staff had completed their Mandatory training at the time of our inspection.

Safeguarding

Staff understood how to protect patients from abuse and the service worked with other agencies to do so. Although staff had training on how to recognise and report abuse and they knew how to apply it, the service did not have access to a level three trained safeguarding lead.

There were systems, processes to keep both adults and children safe from abuse. The safeguarding policy was in date and described the definition of abuse and neglect, who might be at risk, general indicators, and what actions to take if staff suspected abuse. The policy was easily accessible in a service information folder and included contact details for safeguarding leads, the local authority, and emergency out of hours services.

Staff we spoke with had a clear understanding about safeguarding, knew what the signs of abuse might be, and where to access support if they had any concerns. They were confident about how to escalate concerns to the safeguarding lead.

Not all staff had received training specific for their role to the required level, on how to recognise and report abuse.

Staff had training in safeguarding adults and children in levels one and two. Although the service, did not provide ultrasound services to adolescents under the age of 16 years, children frequently attended ultrasound baby scan appointments with their mothers. Sonographers had undertaken safeguarding children's training level two. This met the intercollegiate guidance 'Safeguarding children and young people: roles and competencies for health care staff' (January 2019). However, the registered manager was the lead for adults and children safeguarding and had not undertaken any level three safeguarding training. There was no service level agreement in place for the service to access someone who had undergone this level of training. This was not in line with national guidance on safeguarding children. After our inspection two senior members of the management team underwent safeguarding children level 3 online training. However, there was still not a safeguarding adults' level 3 trained person within the organisation.

Staff knew how to make a safeguarding referral and who to inform if they had concerns.

Requires improvement

Diagnostic imaging

Staff knew what to look for and said they would report a safeguarding concern to the registered manager and/or assistant manager. Both the registered manager and assistant manager knew how to make safeguarding referrals. There had been no safeguarding referrals since the company became operational in 2017.

Chaperones were available during scanning clinics. Women who attended alone were always accompanied by a chaperone during their baby scanning procedure.

Female genital mutilation (FGM) information was contained within the safeguarding policy and was in line with the Department of Health female genital mutilation and safeguarding guidance for professionals (2016). Staff were clear about how they escalated any concerns they had. FGM was part of the safeguarding mandatory training programme.

All staff working in the service had a Disclosure and Barring Service (DBS). This was to help detect and prevent unsuitable people from working with vulnerable groups, including children.

Cleanliness, infection control and hygiene

The service mostly controlled infection risk well. Staff kept themselves, equipment and the premises clean. However, there was no evidence of audits undertaken to monitor or improve infection prevention and control.

All staff had received mandatory training in infection prevention and control. There was an infection control policy which was in date and in line with national guidance.

All clinical areas were visibly clean and had suitable furnishings which were clean and well-maintained.

Staff cleaned all equipment after each patient. The ultrasound transducer was cleaned between each patient, and disposable sheaths were used during intimate procedures. The clinic rooms were deep cleaned every week. A record was maintained of daily and weekly cleaning. Regular cleaning audits were undertaken which showed all areas consistently met cleanliness standards. The assistant manager was the lead infection control person and had the responsibility of maintaining a cleaning rota and all staff were allocated cleaning duties.

Staff followed infection control principles including the use of personal protective equipment (PPE).

Handwashing facilities were available, and staff followed 'arms bare below the elbows' practice as set out in the services infection and control policy. We observed staff washing their hands between patients in line with hand hygiene guidance. Gloves and aprons were used appropriately by staff.

However, we saw no evidence of regular hand hygiene audits.

A disposable paper towel was used to cover the examination couch during the scanning procedure. This was changed between each patient.

Staff told us that if there was a patient with a known infection, they would schedule the appointment for the end of the session. In addition, all equipment would be cleaned thoroughly with disinfectant after the patient had been seen. There had been no instances of healthcare acquired infections since the service opened.

COSHH (control of substances hazardous to health) chemicals were locked away and a spills kit for the safe clean-up and disposal of bodily fluids such as blood and vomit was available.

Environment and equipment.

The service mainly had suitable premises and equipment which were looked after and were well maintained. However, there was not an accessible toilet for patients to use.

The scanning room was spacious and had good lighting which dimmed to allow ultrasound scans to be clearly seen. Flooring throughout the clinic was well maintained and visibly clean. and in line with national requirements ('Health Building Note 00-10 Part A: Flooring', Department of Health, 2013). Environmental risk assessments, including health and safety, fire, and first aid facilities were in place. These were prominently displayed throughout the premises.

There were two entrances to the premises with customer parking provided. A ramp was available to provide access to wheelchair users. Through the front entrance there was a reception desk and waiting area. There was a private office behind the reception for patients to view their images and to talk privately with staff.

Requires improvement

Diagnostic imaging

There was one scanning room on the ground floor and two spacious waiting areas with sofas, chairs and a television. There was a second scanning room on the first floor and a waiting room. Scanning Rooms were private and secure. There was a small play area at the rear of the waiting area with toys provided.

Female and male toilets and baby changing facilities were located upstairs. The service did not provide a disabled toilet. Patients were advised of this when they booked to attend to enable them to make an informed choice about whether the facilities provided were appropriate for their needs.

The service had enough suitable equipment to help them to safely care for service users.

Clinic store cupboards were stocked with equipment needed for ultrasound such as gels, ultrasound probes and sheaths. All gels and sheath covers we checked were within their expiry date. Staff had access to all the equipment and supplies they needed to provide the service. Storage rooms were marked private with 'No Access to Public'.

Staff carried out safety checks of specialist equipment.

Scanning machines were maintained and serviced by professional engineers under maintenance contract and records were kept. All portable electrical appliances were electrical tested and were in date.

Fire extinguishers were accessible and there was a contract in place with a company to ensure fire extinguishers were regularly serviced. Smoke detectors were in place throughout the building and during the visit one detector was heard tweeting to signal that the battery needed replacement. The provider told us they would replace this after the inspection.

Waste was handled and disposed of in a way that kept people safe. Staff used the correct system to handle and sort non-clinical waste. The service had a contract with a waste management company for the collection and disposal of hazardous waste.

Assessing and responding to patient risk

The service had some arrangements in place to assess and manage risks to patients, however the process for risk assessing individual patients was not sufficiently robust.

Managers carried out risk assessments on the clinical environment, however individual patient risk assessments were limited to a brief clinical history of why they were attending included on the ultrasound report. Patients were made aware of this beforehand by signing a disclaimer to say they would report to the practitioner if they had any allergies, skin conditions or physical/mental conditions prior to the scan. However, there was no reference to reporting other health conditions and no evidence that the practitioner checked that the patient had understood the disclaimer and had no conditions to report before undergoing the scan. Therefore, we were not assured that there was a robust system in place that ensured all patient risks were adequately assessed and managed.

Staff followed safety guidance when using ultra sound machines, including using the 'Paused and Checked' checklist devised by the British Medical Ultrasound Society (BMUS) and Society of Radiographers. This guidance ensured sonographers carried out extra confirmation that they were about to carry out the correct procedure, on the correct patient.

Scan reports were completed immediately after the scan had taken place. Patients were given copies of their scan reports to share with their general practitioner (GP) or other healthcare professional.

Staff shared key information to keep patients safe when handing over their care to others.

For baby scanning services, pathways had been developed to follow in the event problems were detected with the foetus or mother. We spoke with the midwife sonographer who had helped develop these pathways. A recent example where a pathway had been used was when a woman presented with an ectopic pregnancy. Although the service did not routinely make referrals, in the event of an emergency, patients were told to immediately go to hospital.

Women using the baby scanning service were advised about the importance of still attending their NHS scans and appointments. The sonographers made sure women understood that the ultrasound scans they performed were in addition to the routine care they received as part of their maternity pathway. The terms and conditions for

the baby scanning service clearly explained this. Women were asked to sign a contract to confirm they had read and understood the terms and conditions before any service was undertaken.

Patients using the diagnostic scanning service, for example who needed to have a scan of their bladder, were provided with written reports and scan images. Patients had the responsibility of sharing these reports with their GP or other healthcare provider.

Staff had guidance in place to follow if a patient became ill. Staff said that they would call 999.

All staff had up to date training in basic life support and first aid training.

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 care team comprised of sonographers and extra staff who worked as reception staff and chaperones. This ensured the smooth running of clinics so that patients were well taken care of during their appointment.

The service had enough staff to keep patients who used the service safe.

The service employed 12 staff in total. There were four whole time equivalent (WTE) joint receptionists and chaperones and one WTE sonographer. There were also three part-time receptionists employed. Several staff were on zero hours contracts and this included one receptionist and three sonographers. Two of the three sonographers also worked for the NHS.

From August 2018 to August 2019, one receptionist and one sonographer had joined the service and one receptionist had left. The staff sickness rate was 1%, which was lower than the service target.

The service ensured all staff who work for them had the necessary safety checks undertaken, including Disclosure and Barring Service (DBS) and references during recruitment.

Sonographers were employed based on their area of expertise and only carried out scans in areas of their competence. The service did not use any bank or agency staff, and at the time of our inspection, there were no vacancies.

Records

Staff kept records of patient's personal details. Records were clear, up-to-date and easily available to all staff providing care. Staff had paper and electronic records.

Patients notes were comprehensive, and all staff could access them easily. Information included patient's contact details, consent to scans and scan reports.

Records were stored securely. The service did not send information to any other parties apart from in emergency situations. Copies of scan results were given to patients to share with GP's and other health professionals if required.

Images were saved on the ultrasound machine for six months. They were then removed and stored on a removable hard drive which was kept in a secured and locked cabinet.

Terms and conditions and scan reports were stored away in a locked area only accessible to management staff. To date the service had not destroyed any records.

The service was not registered with the Information Commissioner's Office (ICO); however, they were fully compliant with the General Data Protection Regulation (GDPR) and kept up to date with updates from the ICO. The service provided evidence that after the inspection, that it had registered with the ICO.

Medicines

The service did not use any controlled drugs or medicines.

Incidents

The service managed patient safety incidents well. Staff recognised incidents and reported them appropriately. Managers investigated incidents and share lessons learned with the whole team. When things went wrong, staff told us they apologised and give patients honest information and suitable support.

Requires improvement

Diagnostic imaging

Staff knew what incidents to report and how to report them. Accidents and incidents were documented and maintained in the staff incident book. All staff we spoke with described the process for reporting incidents and told us they understood incidents to be things such as a near miss, when something went wrong or had the potential to go wrong. Staff said they discussed incidents with the registered manager and were encouraged to talk to each other about it.

The service had not had any never events since it opened. 'Never events' are serious incidents that are wholly preventable as guidance or safety recommendations that provide strong systemic protective barriers are available at a national level and should have been implemented by all healthcare providers. In accordance with the Serious Incident Framework 2015, the service did not report any serious incidents since the company opened in October 2018.

Regulation 20 of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014 is a regulation introduced in November 2014. This regulation requires the organisation to be open and transparent when things go wrong in relation to their care and where the patient suffers harm or could suffer harm. Staff understood the duty of candour and the need for being open and honest with patients and their families if errors occurred. The registered manager could explain the process they would undertake if they needed to implement the duty of candour following an incident, which met the requirements. However, at the time of our inspection, they had not needed to do this.

Are diagnostic imaging services effective?

We did not rate effective for this service

Evidence-based care and treatment

The service mostly provided care and treatment based on national guidance and evidence of its effectiveness. Managers checked to make sure staff followed guidance. The service followed national guidance written by the Society and College of Radiographers (SCoR) and British Medical Ultrasound Society (BMUS) ('Guidelines for Professional Ultrasound Practice', December 2018). Sonographers followed the 'ALARA' (as low as reasonably achievable) principles. Where possible, the sonographers completed ultrasound scans within 15 minutes to help reduce ultrasound patient dose. However, one sonographer told us they did not routinely time their scans, and therefore were unable to say how many patients had scans which exceeded 15 minutes. This was not in line with best practice.

Staff told us they adhered to the 'Paused and Checked' checklist, which was designed as a ready reminder of the checks to be undertaken prior to any ultrasound procedure. This was in line with national standards outlined by the SCoR and the BMUS.

Staff followed policies to plan and deliver high quality care according to evidence-based practice and national guidance. Local policies were in place and were in line with current national guidance. Policies included: early pregnancy scans, gender scan, breaking bad news guidance, foetal anomaly scan guidance and growth and presentation scans. Managers told us they regularly checked and audited a sample of each scan type to ensure guidance was being followed.

Nutrition and hydration

Staff gave patients and people accompanying them drinks as required. The service provided complimentary cold drinks to patients. Other drinks were available to purchase, for example, if family members wanted a drink. However, due to the nature of the service and the limited amount of time patients spent there, food and drink was not routinely offered.

Patients were advised in their appointment letter if they were required to have a full bladder prior to their ultrasound scan and if so, to ensure they had drunk plenty of fluids prior to their appointment.

Pain relief

Staff continually assessed the patients comfort during each procedure. The service did not offer pain relief or formally assess pain as most procedures were pain free. Staff said some patients experienced low level discomfort depending on the type of ultrasound scan they were having. Sonographers were aware of procedures which may feel uncomfortable for patients, and always discussed this in advance with the patient.

Patient outcomes

Requires improvement

Diagnostic imaging

The service monitored scan image quality outcomes.
The service carried out peer review audits. These were undertaken in line with guidance issued by the British Medical Ultrasound Society (BMUS). This guidance recommends that peer review audits are completed using the ultrasound image and the written report. To ensure quality assurance, audits were taken from a sample of five reports of each scan type chosen at random every six months. Sonographers told us that managers contacted them if any images or reports were unclear, and if they were required to be done again. Staff did not keep records of the number or percentage of repeat scans required. However, we were told that these were usually for keepsake baby scanning images, where patients had wanted a better image.

Audits were completed on the baby scanning images to ensure that woman received correct, and relevant information. Images were audited for presence of structures, measurements, quality of image, patients name, due date, date of scan, and name of clinic. Audits were also carried out on printed images. This audit was to ensure that the quality of printing was of the highest standard. This quality audit was performed at every scan before the pictures were passed over to the woman. If staff felt that the print quality was not of the highest standard, the image was then reprinted to correct the error.

A hard copy of each report was kept and filed. The original report was given directly to the woman including ensuring that any questions had been answered and that they understood what was explained in the report. Where anomalies or abnormalities had been detected, these were clearly recorded on the report along with advice to seek medical attention either via emergency services, midwife or GP.

Written reports were clear and legible, with report dates, and the sonographers name, plus the chaperones name if appropriate. All reports included the patient's details, including their name, contact number and date of birth as provided by the patient on the terms and conditions.

The service expected all images provided to patients to be of the best quality. For women having baby scans, this included trying to ensure the baby was in the best position for a good image to be obtained. For most of the scans, the images were offered as a keepsake item and not meant to be used as medical advice.

Competent staff

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

A minimum of four weeks induction training was given to new staff. This included for example training in health and safety, infection control, safeguarding, chaperoning, and data protection. All policies and procedures were also provided for new staff to familiarise themselves with. Regular assessments were completed, and additional training courses were provided for relevant staff.

Sonographers were not required to be registered with the Health and Care Professions Council (HCPC), however some of the sonographers working in the service were members of the Society of Radiographers. This professional body publish professional guidance documents and supports clinicians through education and research. In addition, membership provided staff with professional indemnity insurance. The midwife sonographer was registered with the Nursing and Midwifery Council (NMC).

The service employed staff based on job related criteria and their ability to perform the job. Two of the three sonographers also worked for the NHS. All three sonographers had the skills and experience to undertake scans effectively.

All staff received annual appraisals and supervision, however staff who worked predominantly in the NHS, and were self-employed received their annual appraisal during their substantive employment.

Multidisciplinary working

The staff worked together as a team to care for patients and those who accompanied them.

There was a good working relationship between staff members and staff were proud and happy to work for the service. The registered manager, the assistant manager, sonographers, chaperones and receptionists all supported each other as one professional team.

The service did not make referrals directly but, where anomalies were identified, the service would advise patients to contact their general practitioner

(GP)/midwife/hospital with a copy of their ultrasound report. When obstetric emergencies were diagnosed the service advised woman to attend the accident and emergency department of the nearest hospital without delay.

Seven-day services

The service usually ran clinics seven days per week mornings and evenings except for Monday when there were no morning clinics. Patients were able to obtain same day appointments.

Consent and Mental Capacity Act

Staff understood their roles and responsibilities under the Mental Health Act 1983 and the Mental Capacity Act 2005. They knew how to support patients experiencing mental ill health and those who lacked the capacity to make decisions about their care. Staff received training in the Mental capacity Act 2005 as part of their annual mandatory training programme.

Staff gained consent from patients for their care and treatment in line with legislation and guidance. Staff clearly recorded consent in the patients' records. All patients received written information to read and sign before their scan appointment, which was available in different languages. This information included terms and conditions, such as scan limitations, consent, prices and use of data. Staff checked the form was signed before carrying out the scan. There was a separate consent form used for transvaginal scans in line guidance from the Society and College of Radiographers and the British Medical Ultrasound Society Guidelines for Professional Ultrasound Practice.

The service was transparent with its pricing and these were displayed on leaflets, on the internet, on the premises and discussed with potential patients on the phone.

Staff understood how and when to assess whether patients had the capacity to make decisions about their care. Staff we spoke with were able explain their responsibility to gain consent from patients before carrying out any procedure and were aware of the procedure for assessing whether patients had capacity to consent to their treatment. They followed the service policy and procedures when a patient could not give consent.

Are diagnostic imaging services caring?

Good

We rated caring as **good**.

Compassionate care

Staff cared for patients with compassion. Patients confirmed that staff treated them well and with kindness.

Staff were discreet and responsive when caring for patients. Staff spoke in a kind and respectful way. Patients could speak privately with reception staff in a private area of reception.

Staff were friendly and built a rapport with patients and their families, which put them at ease and encouraged a calm and reassuring environment.

Staff treated patients with dignity and respect and provided compassion throughout their scan journey. The sonographer offered good explanations of the scan being carried out and took time to answer any questions. The scanning procedure was not rushed, and patients were given plenty of time to ask questions.

Although the service did not formally request feedback from patients or analyse their satisfaction score, we did see positive comments in the service's comments and suggestion book and on its' social media pages. Comments were made like 'Brilliant experience, service is excellent' and 'very happy with service, lovely people, would recommend'.

Emotional support

Staff provided emotional support to patients to minimise their distress.

The sonographer was trained to break any adverse news in an articulate, sensitive manner and all staff had received training in how to support patients when they received bad news.

Requires improvement

Diagnostic imaging

Staff told us how they handled bad news in a caring and understanding way. They said they would offer comfort to patients who might be distressed after having a scan. Staff recognised that women, whose baby scan resulted in bad news, were particularly vulnerable and therefore extra care was provided for this group of patients. Staff explained that women reacted differently and while some wanted to leave straight away, others wanted to sit privately or to talk to staff about their scan for longer. Staff said they were always guided by what the patients wanted.

Understanding and involvement of patients and those close to them

Staff involved patients and those close to them in decisions about their care and treatment.

Staff made sure patients understood their care and the purpose of the scans provided and the limitations of the scan. We were told that each patient was contacted prior to their appointment to discuss the planned scan and to confirm the services terms and conditions. This was discussed again immediately prior to the scan taking place.

Patients were welcome to bring family to attend scans and for baby scans, whole families could attend. Chairs were arranged inside the treatment room so that everyone was able to see the bay scan monitor. We observed a sonographer and chaperone explaining to a woman and her partner what was happening during a scan procedure. The sonographer took time to show them details of the scan and findings. She asked them if they wanted to know the sex of the baby before she told them. Feedback from patients confirmed that staff were thorough and took time to explain procedures to them and that they felt comfortable and reassured.

Are diagnostic imaging services responsive?

Requires improvement

We rated responsive as **requires improvement.**

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. Facilities and premises were appropriate for the services being delivered. The environment was appropriate and welcoming. There were comfortable seating areas, toilet facilities (although no accessible toilet) and baby changing facilities. The reception area was visibly clean and tidy, and the sitting area had access to magazines and children's toys. The clinic had a car park and was located close to public transport facilities.

Enquiries and appointment requests were responded to with a personal telephone call during which any questions were answered. Patients were provided with appropriate information about pricing and scan options before their visit.

The service mainly provided pregnancy reassurance scans to women. This included, 2D anomaly scans, growth and presentation scans, gender scans and 4D multi-scans. The service provided planned baby keepsake scans for patients at their convenience. However, the service also offered a variety of other scans to men and women, including for example, bladder and kidney scans, abdominal scans and scans of arteries. Sonographers told us these scans were provided privately to patients while they waited for an appointment with an NHS provider.

Meeting people's individual needs

The service mostly took account of most patients' individual needs, although the service did not provide translation services for all patients in order to keep them safe, or accessible toilet facilities for patients who needed them.

Some patients' individual needs and preferences were considered in the delivery of the service. Staff asked if patients if they had any special needs or requirements during the booking process.

Staff explained how they could make adjustments for patients, including adjustments to the service for patients with physical disabilities and patients with visual and hearing impairments. A staff member explained how the service had met the specific needs of a transgender person and how women with surrogate pregnancies were cared for along with the parents of the baby.

Diagnostic imaging

There was access for people with disabilities including wheelchair users. This included a ramp for access through the front door and a ground floor scan room. However, there was no accessible toilet on the ground floor.

The service did not have access to foreign language interpreters, although staff explained that they knew how to operate an online translator application. Also, two staff members could speak Urdu and Punjabi and another staff member could speak Bengali. We were told that most of the women using the baby scanning service were usually accompanied by a friend or relative who could speak English and who would act as a translator. However, the use of friends and family as translators is not best practice, therefore we cannot be assured that these patients received accurate translation, which poses a risk to them receiving safe care. After the inspection the service advised us that they had installed a telephone translation service for both their staff and patients to use.

Ultrasound scans were carried out in a private room ensuring patient conversations were not overheard. We observed that prior to the scan commencing, the sonographer explained the procedure and asked the patient if they were okay to proceed. The door to the ultrasound room was closed when the appointment was in progress.

Where women had suffered a miscarriage, they were provided with contact details for the 'Miscarriage Association' and encouraged to contact this organisation for support. These women were also advised to contact their general practitioner (GP) or midwife as soon as possible.

Chaperones were provided to woman patients routinely. This helped the smooth running of clinics and offered the patient some assurance. Chaperones took time to ensure women were comfortable throughout the procedure. We saw a chaperone helping a woman on to the bed and asking if she was in a comfortable position. Staff understood the services chaperone policy and explained that as a chaperone it was their duty to offer patients support and ensure they were safely cared for.

Staff provided person-centred care. A staff member explained that each patient was different and had different expectations. Religious needs were acknowledged along with individual personal preferences. The registered manager told us that the service did not discriminate on any grounds. This included age, disability, gender, gender reassignment, pregnancy and maternity status, race, religion or belief and sexual orientation.

The service had an equality and diversity policy in place and staff had received training in equality and diversity as part of their mandatory training programme.

Access and flow

People could access the service when they wanted it.

The service was flexible and provided a choice of scan options and appointment times. Appointment systems were simple to use either via the service online system or by telephoning the booking line. Same day appointments were sometimes available. Nearly all (97%) of patients were scanned within five days of a request for an appointment. The service did not receive urgent referrals and all patients were self-referred.

The service usually ran to time. However, if there was a delay, patients were made aware immediately and kept well informed of the situation. We were told this did not happen very often and was usually due to babies being positioned in difficult positions which made it difficult to complete a scan. The service did not record the number of patients who had delayed appointments.

The service did not audit the number of patients who did not attend (DNA) their appointments. We were told that as all patients were self-funded, most did arrive for their scan. Patients could usually change scan times if necessary. The scan reports were written during the appointment and there were no delays for patients in receiving their reports.

Learning from complaints and concerns

The service investigated complaints and shared the results with all staff. Where possible, complaints were resolved at the time they were made, and free rescans were offered if the scan could not be completed. However, the response to complaints were not documented and themes were not identified and shared in order to enable the service to improve.

From August 2018 to August 2019, the service received nine complaints one of which was a formal complaint.

Requires improvement

Diagnostic imaging

The service had a complaints policy which was available on their website and gave clear instructions on how to raise complaints and concerns, including contact details of to whom and where to send the complaint to.

The service investigated all complaints. We were told patients who had complained were contacted and invited back to the clinic to discuss their concerns, where appropriate. The registered manager said they would apologise and find a way of making amends. Also, staff tried to identify what could be done to make sure the problem did not happen again.

The service had received one formal complaint within the last 12 months. There was no record of the investigation or outcome, although staff were able to explain how the complaint had been addressed, and that the patient was happy with the outcome. The complainant had been contacted within 24 hours to acknowledge receipt of their complaint, which had been investigated and resolved within three days. Staff also gave us another example of how concerns had been raised during an early pregnancy scan and how staff had learned from this and actioned changes.

The provider told us that if they received a concern in respect of a scan not being as clear as expected, they examined the quality of the scan and if deemed that the scan could be improved, a further scan was offered free of charge. Where baby scan images were undertaken and the baby was not lying in a position where a good image could be obtained, for example the face could not be seen, rescans were undertaken free of charge. However, staff told us they tried to encourage the baby to change position by getting women to walk around and drink water, which had sometimes helped.

Where patients complained about the time scans had taken, managers investigated the images for the time stamp on the scan and on the backup machine to ensure the patients received their full allotted time. Free re-scans were offered where less time was given initially. The service did not keep separate records of the number of rescans which had been required and for what reason in order to use this information to monitor quality and drive improvement.

All complaints received were from the baby scanning service and most were about the quality of the images produced. None of the complaints were about the service's diagnostic imaging.

The service was open to suggestions and welcomed feedback from patients as they said this was an opportunity to improve their service. Staff gave an example of where they had responded to feedback. They had removed an image of a baby from their quite room which they used to deliver bad or distressing news. The image was removed so as not to cause unnecessary grief to women who may have lost a baby.

Are diagnostic imaging services well-led?

Requires improvement

We rated well-led as **requires improvement.**

Leadership

Managers at all levels in the service mostly had the right skills and abilities to run a service providing mostly high-quality sustainable care.

Managerial leadership was provided by the registered manager (RM) and an assistant manager who deputised in the RM's absence, and who was the named individual. The registered manager was fully involved with the day-to-day running and handling of the clinic. The registered manager worked across two of the providers locations.

Although leaders had the capacity, capability and experience to lead effectively, some quality measures were not in place. This included, for example records were not kept of the number of patients whose appointment was delayed. However, staff told us that the registered manager and assistant manager were very approachable and supportive and provided strong direction for the service. Leaders understood the challenges to good quality care and could identify actions needed to address them.

Vision and strategy

Requires improvement

Diagnostic imaging

The service had a vision for what it wanted to achieve and workable plans to turn it into action, however they were working towards producing a written strategy.

Leaders shared their service vision with staff. Staff told us they all worked towards the common goal of patient satisfaction. The registered manager told us that there was not a current written strategy. However, they aimed to develop written strategic objectives to meet the current and longer-term service vision over time. The services main strategy was to provide a sustainable high-quality business.

After the inspection the service provided a basic vision and strategy document. This was to be reviewed and progress monitored at future partners meetings.

Culture

Managers across the service promoted a positive culture that supported and valued staff, creating a sense of common purpose based on shared values.

Staff said they focussed on creating a positive experience for patients and for their colleagues. The service had an open and honest culture and a 'no blame' approach. Staff reported feeling supported by the registered manager, describing them as accessible and supportive. Staff all worked together as a 'family' and were devoted to running the service to very high standards and to ensuring patients were always happy with their standard of care.

Governance

The service used some measures to improve service quality, however, there were some gaps in the delivery, recording and implementation of quality monitoring.

The registered manager had overall responsibility for clinical governance and quality monitoring and was supported by an assistant manager who managed the service in their absence. This included investigating incidents and responding to patient complaints. Although complaints were investigated, there was no log of actions.

Ultrasound scans were not timed and therefore the service was unaware of how many patients had scans which had exceeded the recommended 15 minute maximum exposure. The service did not keep accurate records of the number of each type of scan it had carried out. For example, how many bladder or kidney scans had been done.

Some policies and procedures were in place for the safe and effective running of the service. Staff knew about the policies and had signed to indicate that they had read the policies. However, policies did not include the need to time scans and audits were not carried out on the number of scans which exceeded 15 minutes, for example.

Some audits were carried out, for example on scan reports, staff competencies, infection control and health and safety audits, however we did not see a comprehensive audit plan with results and associated action plans.

The service held regular staff meetings, however these were not recorded and there were no records or minutes of the meetings. We were told these meeting would be minuted in future. After our inspection the service provided minutes of team meetings held in March and April 2020. Although this was an improvement, the minutes did not contain sufficient detail that a member of staff absent from the meeting would be able to understand the discussion or any actions taken

The provider had taken out insurance for the service and this was in date. There was a robust staff recruitment procedure, for example we saw the service had carried out all the usual checks including references and DBS checks.

Managing risks, issues and performance

The service did not always use systems to identify potential problems, deal with those problems or to cope with both the expected and unexpected and there was no documented business continuity plan.

There was no risk register for the service, however, internal and external risk assessments were completed for identified risks. For example, a fire risk assessment had been completed by an external company.

The service did not have a documented business continuity plan, or risk assessment. However, the

registered manager told us they had informal plans in place for things like power cuts, or staff sickness. We were told the service continually adapted according to external risks which arose from time to time.

The service did not use formal key performance indicators to monitor performance. However, they did use patient feedback, complaints, and staff feedback to help identify any necessary improvements and ensure they provided an effective service.

The registered manager and assistant manager were aware of the requirements for reporting incidents to the CQC using the statutory notification route, under Regulation 18 of the Care Quality Commission (Registration) Regulations 2009.

The service carried out various audits including annual health and safety risks, six monthly image audits and monthly staff audits. Staff audits included key performance indicators. However, at the time of our inspection, these audits were only carried out on three members of staff. The registered manager told us that in future, all staff who worked in the service would be audited.

Managing information

The service collected and managed some information to support all its activities, using secure systems with security safeguards.

The service was aware of the requirements of managing patient's personal information in accordance with relevant legislation and regulations. General Data Protection Regulations (GDPR) had been reviewed to ensure the service was operating within them.

The assistant manager was the data controller for the service and managed records effectively. Staff had received training on information governance and data protection as part of their mandatory training programme.

Patients records and scan reports were easily accessible and were kept secure. Paper records were stored within a locked room, and all electronic records and systems were password protected. However, the service did not keep records of the number and type of every different scan they carried out.

Engagement

The service engaged well with patients and staff. There was limited opportunity for engagement with the public to plan and manage appropriate services.

Staff told us leaders of the service were fully engaged with them, and that this was evident through the support provided with mandatory training and impromptu training sessions with the sonographers and managers.

Staff said they engaged well with patients who used the service and that full information was provided to them before and during their appointment. Feedback from patients confirmed that they felt informed and supported during their visit.

Women using the service's early pregnancy reassurance scan service were provided with details about other support agencies available, should they need help following a scan which identified a miscarriage had occurred, or other foetal abnormality.

All scans were carried out at the request of patients. As such, the service was not required to engage with partner organisations or the public generally and there were no contractual agreements in place with other local providers.

Learning, continuous improvement and innovation

Although the service shared learning amongst staff and made improvements to the service following feedback from patients, actions were not formally logged so that improvements could be tracked.

The registered manager told us about the immediate actions they planned to undertake to address some of the concerns we raised during the inspection. For example, future staff meetings would be documented and minuted, and a complaints log would be instigated.

The service had recently won an award for being the "best practice representative" in its industry in the 2020 Parliamentary Review. The title was awarded after an assessment by the Parliamentary Review committee.

Outstanding practice and areas for improvement

Areas for improvement

Action the provider SHOULD take to improve

- The provider should ensure that they have access to a member of staff who has completed level three adults and children's safeguarding training. (Regulation 13).
- The provider should ensure a risk assessment is documented for each individual patient.
- The provider should ensure that the lack of accessible toilet provision is made clear to patients before they attend.
- The provider should ensure that customer feedback is sought and analysed
- The provider should ensure they implement an audit plan.
- The provider should ensure they time their ultra sound scans and record those which exceed 15 minutes. (Regulation 12)
- The provider should ensure a risk register is in place for the service. (Regulation 12)
- The provider should ensure that translation services are not provided by family members.
- The provider should consider formalising a business continuity plan
- The provider should consider documenting all team meetings and keeping minutes from these.
- The provider should consider ensuring that any action taken following a complaint or concern is recorded.