A 4D 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	Good
Are services safe?	Good
Are services effective?	
Are services caring?	Good
Are services responsive?	Good
Are services well-led?	Requires improvement

Overall summary

A 4D Baby is operated by Alison Margaret Hines. The service carries out ultrasound baby scanning for keepsakes. Facilities include a scanning room, waiting area, and toilet facilities.

The service provides ultrasound baby imaging for pregnant women from the gestation of seven weeks. We inspected the single speciality service.

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.

Summary of findings

The only service provided at this location was ultrasound baby scanning.

Services we rate

We rated it as **Good** overall. We found areas of good practice:

- Staff understood how to protect patients from abuse and the service worked well with other agencies to do so.
- The service controlled infection risk well and they had suitable premises and equipment and looked after them well.
- Staff assessed risks to service users, they kept clear records and asked for support when necessary. Staff kept records of service user' appointments, referrals to NHS services and completed scan consent documents.
- The service generally had enough staff with the right qualifications, skills and experience to keep people safe from avoidable harm and to provide the right care.
- The service provided care and treatment based on national guidance and evidence of its effectiveness. Managers monitored the effectiveness of care and treatment and used the findings to improve the service.
- Managers appraised staff's work performance and held supervision meetings with them to provide support and monitor the effectiveness of the service.
- Staff of different kinds worked together as a team to benefit service users. Staff understood how and when to assess whether a patient had the capacity to make decisions about their care.
- Staff cared for patients with compassion. Feedback from patients confirmed that staff treated them well and with kindness. Staff involved patients and those close to them in decisions about their care and treatment and provided emotional support to patients to minimise their distress.
- The service planned and provided services in a way that met the needs of local people. The service took account of patients' individual needs and people could access the service when they needed it.
- The service treated concerns and complaints seriously, investigated them and learned lessons from the results, and shared these with all staff.
- The registered manager generally had the right skills and abilities to run a service providing high-quality sustainable care. The registered manager of the service promoted a positive culture that supported and valued staff.
- The service had a vision for what it wanted to achieve and workable plans to turn it into action. Staff understood and supported the vision of the service.
- The service collected, analysed, managed and used information well and systematically improved service quality and safeguarded high standards of care. The service had systems to identify risks, plan to eliminate or reduce them.
- The service engaged well with patients, staff, the public and local organisations to plan and manage appropriate services, and collaborated with partner organisations effectively.

We found areas of practice that require improvement:

- There were inconsistencies with mandatory training requirements for sonography assistants. Record showed that one of the sonography assistants completed mandatory training through their NHS employment and the other sonography assistant did not work for the NHS and did not have a mandatory training programme to complete.

Following this inspection, we told the provider that it that it must make improvements, even though a regulation had not been breached, to help the service improve.

- The service should ensure that all staff complete mandatory training and reduce inconsistencies between staff in their mandatory training requirements.

Amanda Stanford

Deputy Chief Inspector of Hospitals (on behalf of the Chief Inspector of Hospitals)

Summary of findings

Our judgements about each of the main services

Service	Rating	Summary of each main service
Diagnostic imaging	Good 	The service provided baby keepsake scanning services to women. We rated the A 4D Baby as good for safe, caring and responsive. We rated well-led as requires improvement as there was a lack of systems in place to ensure all staff had access to a mandatory training programme. We do not currently rate diagnostic imaging services for effective.

Summary of findings

Contents

Good

Location name here

Services we looked at
Diagnostic imaging

Summary of this inspection

Background to A 4D Baby

A 4D Baby is operated by Alison Margaret Hines. The service opened in 2005 to provide keepsake and reassurance baby scans to women. When the service opened it was a partnership organisation which changed to the sole provider in 2014. It is a private service in Martlesham Heath, Suffolk and primarily serves the communities of Suffolk with some service users from the surrounding counties of Norfolk and Essex.

The service provides:

- Early reassurance scans from 7 weeks
- 12 week baby scans
- 2D/4D sexing scans from 15 weeks to 23 weeks
- High definition sexing scans from 15 weeks to 23 weeks
- 4D baby scans from 26 weeks to 28 weeks

All scans included four black and white images with the exception of basic gender scans from 15 weeks that was 2D and had 2 thermal images. The service offered 4D scans with CD Rom/USB images and heartbeat recordings included from 15 weeks.

The service has had a registered manager in post since 2014 when the service was registered with the Care Quality Commission.

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.

How we carried out this inspection

We inspected this service using our comprehensive inspection methodology. We carried out the short noticed announced part of the inspection on 13 December 2018. This was the first time this service had been inspected.

Information about A 4D Baby

The service is located in a converted retail unit situated in a shopping centre in Martlesham Heath with one scanning room and is registered to provide the following regulated activities:

- Diagnostic and screening procedures.

During the inspection, we visited the scanning facility. We spoke with three staff including sonographers, sonography assistants and senior managers. We spoke with two patients and one relative. During our inspection, we reviewed 10 sets of patient records.

There were no special reviews or investigations of the service ongoing by the CQC at any time during the 12 months before this inspection. This was the service's first inspection since registration with CQC, which found that the service was meeting all standards of quality and safety it was inspected against.

Activity (October 2017 to September 2018)

- In the reporting period April 2018 to November 2018 there were 1,127 scanning procedures recorded at the service; of these 100% were privately funded.

Summary of this inspection

The service employed three part-time sonographers, one midwife sonographer and two sonography assistants with administration responsibilities. The service did not use controlled drugs (CDs).

Track record on safety

- No Never events
- No Clinical incidents
- No serious injuries
- Five complaints

Summary of this inspection

The five questions we ask about services and what we found

We always ask the following five questions of services.

Are services safe?

Good

We rated safe as **Good** because:

- Staff understood how to protect patients from abuse and the service worked well with other agencies to do so.
- The service controlled infection risk well and they had suitable premises and equipment and looked after them well.
- Staff assessed risks to service users, they kept clear records and asked for support when necessary. Staff kept detailed records of service user' appointments, referrals to NHS services and completed scan consent documents.
- 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.

However, we also found:

- Inconsistencies with mandatory training requirements for sonography assistants.

Are services effective?

We do not currently rate diagnostic imaging services for effective, however we found:

- The service provided care and treatment based on national guidance and evidence of its effectiveness. Managers monitored the effectiveness of care and treatment and used the findings to improve the service.
- Managers appraised staff's work performance and held supervision meetings with them to provide support and monitor the effectiveness of the service.
- Staff of different kinds worked together as a team to benefit service users. Staff understood how and when to assess whether a patient had the capacity to make decisions about their care.

Are services caring?

Good

We rated caring as **Good** because:

- Staff cared for patients with compassion. Feedback from patients confirmed that staff treated them well and with kindness.
- Staff provided emotional support to patients to minimise their distress.

Summary of this inspection

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

Are services responsive?

Good

We rated responsive as **Good** because:

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

Are services well-led?

Requires improvement

We rated Well-led as **Requires improvement** because:

- The service did not have adequate systems and processes in place to ensure staff who worked for the service received mandatory training on an annual basis.

However, we also found:

- The registered manager generally had the right skills and abilities to run a service providing high-quality sustainable care. The registered manager of the service promoted a positive culture that supported and valued staff.
- The service had a vision for what it wanted to achieve and workable plans to turn it into action.
- The service systematically improved service quality and safeguarded high standards of care. The service had systems to identify risks, plan to eliminate or reduce them.
- The service collected, analysed, managed and used information well.
- The service engaged well with patients, staff, the public and local organisations to plan and manage appropriate services, and collaborated with partner organisations effectively.

Detailed findings from this inspection

Overview of ratings

Our ratings for this location are:

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

Good

Diagnostic imaging

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

Are diagnostic imaging services safe?

Good

We rated safe as **good.**

Mandatory training

- The service mostly ensured that staff received mandatory training in key skills to all staff, however we found inconsistencies in the requirements for sonography assistants.
- The service did not have robust systems and processes in place to ensure that staff completed mandatory training. The service recognised staff that had completed mandatory training in their substantive NHS roles. However, the service did not have systems and processes in place for members of staff to complete mandatory training if they did not work within the NHS. The registered manager told us that the service did not have a mandatory training programme for staff that were not employed by the local NHS trust.
- Sonographers worked for the service in addition to their roles within the local NHS trust. Staff were asked to provide evidence of mandatory training completion within their key role in the NHS rather than duplicate mandatory training. However, the registered manager did not have systems and processes in place to ensure this evidence was collected. Information provided by the service prior to our inspection showed that 100% of this staff group had completed mandatory training. However, when we reviewed staff records on site that gave details of the mandatory training matrix the documented assurance was missing. The registered manager acknowledged that this information was missing.
- Following our inspection, the registered manager provided evidence to demonstrate that 100% of sonographers had completed the required mandatory training within their NHS role.
- Mandatory training modules completed by sonographers included; equality and diversity, infection control, safeguarding adults level 3, safeguarding children level 2 and 3, health and safety, moving and handling, information governance, fraud awareness, risk and governance, conflict resolution, dementia awareness, learning disabilities, medicines management, end of life care, latex and contact dermatitis, mental capacity and deprivation of liberty, tissue viability, venous thromboembolism (VTE), basic life support and clinical fire safety.
- Sonography assistants undertook induction training in line with health and safety regulations, however did not complete regular mandatory training updates. These staff members had completed safeguarding level one during their induction. One ultrasound assistant had worked within the local NHS trust and had completed mandatory training. However, information provided by the service prior to inspection showed that mandatory training was last completed in 2015. We were concerned as both members of staff employed solely by the service did not complete a programme of mandatory training.
- One member of staff we spoke with told us they had completed the mandatory training through the local NHS trust. Another member of staff we spoke with did not work for the local NHS trust but had completed safeguarding adults and children training as part of their ongoing university studies.

Safeguarding

- Staff understood how to protect patients from abuse and the service worked well with other agencies, to do

so. The service had not made any safeguarding referrals in the 12 months prior to our inspection. All staff completed safeguarding adults and children to level three through the local NHS trust, local authority or the local university. Staff we spoke with had training on how to recognise and report abuse and they knew how to apply it. Staff did complete safeguarding training directly through the service.

- Records we reviewed showed that the registered manager and sonographers had completed safeguarding children training to level three. The service had clear processes in place to raise concerns to the local authority safeguarding board and those of surrounding counties.
- The service did not provide direct care to children; however, the service did have contact with children attending with their parents.
- The service did provide baby scans to young people from 16 years of age. The registered manager told us that all service users from 16 to 18 years of age had to be accompanied by a parent or guardian for the duration of their appointment. Staff understood their responsibility in gaining informed consent and ensuring Gillick competence of this group of service users.
- The service had an up-to-date safeguarding vulnerable adults policy which set out responsibilities of staff and contact details of local authority referral contact details. The policy also provided referral contact details for neighbouring counties.
- Staff we spoke with understood their responsibility to raise any safeguarding concerns and could give examples of the types of concerns they would raise which included female genital mutilation and child sexual exploitation.

Cleanliness, infection control and hygiene

- The service controlled infection risk well. Staff kept themselves, equipment and the premises clean. They used control measures to prevent the spread of infection.
- All of the areas the service used were visibly clean and free from clutter.
- Staff completed cleaning of all areas of the unit both before the day's appointments and at the end of the list which was completed on a daily check sheet. We reviewed records which demonstrated that this cleaning had taken place.
- Staff cleaned equipment and the scanning couch between service users. We observed staff cleaning and sanitising scanning probes and equipment between each appointment.
- The service had an up-to-date infection prevention and control policy in place, which set out staff responsibilities including hand hygiene. Staff observed this policy and we saw staff washing their hands between scanning appointments.
- The service conducted monthly cleanliness and hygiene audits. Records we reviewed demonstrated that the service had achieved 100% from January 2018 to September 2018. The audits reviewed hand hygiene and environmental cleanliness.

Environment and equipment

- The service had suitable premises and equipment and looked after them well. The environment promoted the privacy and dignity of women using the service.
- The service facilities were located in a converted retail unit situated in a shopping centre with one scanning room, waiting room and toilet. The waiting room had an area for child pushchairs and comfortable seating for women and their families to wait for their appointment.
- The service had toilet facilities for service users and their friends and family to use.
- The scanning room was warm with seating for those accompanying women for their appointment. The room had a wall mounted monitor to view the baby scan which displayed the images from the scanning machine. Staff kept the door to the scanning room closed at all times during baby scans to maintain privacy and dignity for service users.
- The service had a storage room located next to the waiting area. Staff locked the storage room at all times.
- The registered manager held a first aid certificate and they were on site during opening hours. A first aid kit was located in the reception area.
- The service maintained their equipment. We reviewed equipment such as, but not limited to, the ultrasound scanner, imaging screen, printing equipment. All items of equipment we checked were up-to-date with safety testing and servicing in line with the manufacturers guidance. The service used an external company to ensure all equipment safety testing and servicing was maintained.

- Fire extinguishers were located appropriately. All fire extinguishers that we reviewed were up-to-date with servicing.
- The service had systems and processes in place to manage domestic waste. The service did not generate any clinical waste, only domestic waste, due to the nature of the service. The service had arrangements in place to manage their domestic waste which was stored outside the rear of the property. The local council was responsible for domestic waste collections on a weekly basis.

Assessing and responding to patient risk

- Staff assessed risks to service users. They kept clear records and asked for support when necessary.
- The service had systems and processes in place to refer women to the local NHS trust or their GP if the scanning process indicated a concern. The service referred women to the early pregnancy unit during their opening hours or to their GP outside of this time.
- The service did not provide diagnostic reports or advice following the baby scan. However, staff signposted women to the local NHS trust, their GP or midwife for diagnostic services.
- Due to the nature of service provided, there was no emergency resuscitation trolley on site. The service carried out only low risk baby ultrasound scans. In the event of a medical emergency or collapse, staff called 999. In addition, a member of staff with first aid training was available at all times during opening hours.
- Staff we spoke with knew the process to refer women to NHS services and kept a copy of referral letters for their records.
- The service sent women information before the scanning appointment which advised them that all scans were souvenirs and keepsakes and were not a substitute for the NHS ultrasound scans or NHS pregnancy care. The pre-scanning information recommended women who had not had a 20-week anomaly scan to book a week day appointment. This meant that the service could contact the relevant medical provider if a concern was detected. We reviewed records of women who had been referred to the local NHS trust due to concerns detected during their baby keepsake scan. The records detailed all relevant information about the services users and the concern.

Staffing

- The service had enough staff with the right qualifications, skills and experience to keep people safe from avoidable harm and to provide the right care and treatment.
- The service employed two senior ultrasound practitioners, two ultrasound practitioners and two ultrasound assistants with additional administrative duties. One of the ultrasound practitioners was a trained midwife.
- Staff worked flexibly to ensure all ultrasound scanning appointments had the core staffing of one ultrasound practitioner and one ultrasound assistant. The busiest time for the service was weekends, so an additional ultrasound assistant was scheduled to work at these busy times.
- Records provided by the service showed there had been no gaps in the staffing numbers from October 2017 to September 2018. The registered manager told us that staff worked flexibly to ensure all scanning sessions were covered. The service did not use bank or agency staff.
- The registered manager monitored staff sickness rates. We reviewed records which demonstrated that the service had no sickness absences for staff from October 2017 to September 2018.
- Staff we spoke with told us that they worked as a team and covered the scanning sessions in the event there was a gap in staffing or to cover holidays and sickness.

Records

- Staff kept detailed records of service users' appointments, referrals to NHS services and completed scan consent documents. Records were clear, up-to-date and easily available to all staff providing ultra sound scans.
- The service had an up-to-date records policy in place for staff to refer to. The policy detailed staff responsibilities and documentation standards, information governance and the retention of records.
- We reviewed 10 baby scan consent records and all of the consent records were completed appropriately by service users and staff. We reviewed two referral letters to NHS services following concerns during a baby keepsake scan. The letters contain the women's details and the details of the concern identified during the baby scan.

Good

Diagnostic imaging

- The service kept completed service user records securely. The consent records and referral letters were archived and stored securely on site. Staff kept completed service user records in a storage box in the locked store room until the registered manager archived the records.
- The service kept baby images securely on the scanning machine for six months and could be retrieved in the event the mother lost or mislaid the images. The images were deleted after the six month period.

Medicines

- The service did not administer, prescribe or use contrast media for any scanning procedures.

Incidents

- Staff recognised incidents and reported them appropriately. Managers investigated incidents and shared lessons learned with the whole team and the wider service. When things went wrong, staff apologised and gave patients honest information and suitable support.
- The service had systems and processes in place to report and manage patient safety incidents. The service used paper forms to report and investigate incidents.
- The service had an up-to-date incident reporting policy to support staff in the correct identification and incident reporting. The policy had a review date and made reference to legislation and best practice guidance.
- The service had no incidents reported from October 2017 to September 2018.
- We spoke with the registered manager about incidents and they told us that they had not had any clinical incidents. Staff recorded any issues with the scanning equipment in a book kept with the machine. Staff knew to record these as formal incidents if a disruption to service occurred as a result of these issues or a risk was identified to the service user or staff. The service had not had any incidents; however, staff knew how to record incidents that required first aid in the accident books. We reviewed the accident book and the equipment record book which confirmed this.
- 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. They reported that the registered manager shared information verbally during their working hours and this would include any information about incidents. They confirmed that no incidents had occurred from October 2017 to September 2018.
- The service had systems and processes in place for duty of candour. 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 of certain notifiable safety incidents and provide reasonable support to that person.
- The service had an up-to-date policy for staff to follow, which set out the responsibilities for staff and the process to follow. Staff we spoke with knew their responsibilities in relation to duty of candour.

Are diagnostic imaging services effective?

We do not currently rate diagnostic imaging services for effective, however we found:

Evidence-based care and treatment

- The service provided care and treatment based on national guidance and evidence of its effectiveness. Managers checked to make sure staff followed guidance through the process of local audit. Staff completed scans in accordance with recommendations set out by British Medical Ultrasound Society and sonographers worked to the code of practice set out the Society of Radiographers.
- The service had a variety of policies in place such as, but not limited to, infection prevention and control, record keeping and consent. All of the policies we reviewed were within their review date and referred to legislation, local and national guidelines and best practice guidance.
- The service had an annual and monthly audit programme which formed the annual audit report. The service audited areas such as hand hygiene, cleanliness, numbers of scans by type, waiting times appointment, turnaround times and referrals to GPs or the local NHS trust. This formed a monthly dashboard.
- The service was inclusive to all pregnant women and there was no discrimination including the on the

grounds of protected characteristics under the Equality Act. The service made reasonable adjustments to be inclusive to all women that wanted souvenir or keepsake baby scans.
- Staff verbally signposted women to NHS services if they experienced symptoms such as vaginal bleeding or pain at the end of their scanning appointment. We observed staff advising women to contact their midwife or GP if they had any concerns.

Nutrition and hydration

- The service was located in small retail area with shops where women could purchase food and drink. Staff provided drinking water on the request of service users.

Patient outcomes

- Managers monitored the effectiveness of care and treatment and used the findings to improve them.
- The service referred 18 women to their GP or the local NHS trust from October 2017 to October 2018 due to the detection of concerns..
- The service audited the number and type of scans undertaken each month, this included the number of service users that were not charged and did not attend rates. The service completed 1,127 baby keepsake scans from October 2017 to September 2018. During this period the service had seven scans resulting in no charge to the service user, where women had presented too early for a reassurance heartbeat scan. The service had seven occasions where women did not attend their appointment. The service did not have assurance systems in place the quality of baby images produced.

Competent staff

- The service generally made sure staff were competent for their roles. The registered managers appraised staff performance and held supervision meetings with them to provide support and monitor the effectiveness of the service.
- All staff members participated in regular appraisal meetings. Each staff member had an appraisal meeting with the registered manager every three months which included their performance, time keeping and their appearance.
- Staff records demonstrated that staff received feedback from the registered manager during these appraisal meetings. We reviewed appraisal records for three staff members, all documents demonstrated that staff were fulfilling their roles.
- The staff survey conducted by the service in 2017/18 showed that 80% of staff that worked for the service felt they had been developed within their roles. The service had five members of staff and of these, one member of staff was on maternity leave.
- Only trained sonographers employed by the service carried out baby scans. All of the sonographers employed by the service worked for the NHS as their main employer where they maintained their practice skills and knowledge required for their role.

Multidisciplinary working

- Staff of different kinds worked together as a team to benefit service users.
- The service had established mechanisms in place to refer women to their GP or the local NHS trust if any concerns were detected during their appointment.
- The service communicated with the local NHS trust and service users GPs by letter and by telephone. The service used printed referral letter templates and hand wrote the women's details and the reason for referral in the designated sections.
- The service displayed information about the local authority safeguarding team contact details in the reception area, this included the contact details for safeguarding teams for neighbouring counties.

Seven-day services

- The service offered baby scan appointments to women in the evenings and on Saturdays so they could access the service at a time that suited them. The service did not open every day, but staff worked in a flexible way to accommodate the needs of service users.
- The service opened at 2pm on, Tuesday, and Thursday on weekdays. The service offered appointments from 9:30 pm on Saturdays. However, the service was flexible if service users requested a scan outside of their normal working hours.

Health promotion

Good

Diagnostic imaging

- Staff provided information to signpost service users to other services appropriate to their needs, due to the baby souvenir and keepsake imaging service provided. The service provided clear written information that the imaging service was not a substitute for antenatal care.
- The service displayed posters and leaflets for local mother and baby support groups and sporting activities for mothers and babies.

Consent and Mental Capacity Act

- Staff understood how and when to assess whether a patient had the capacity to make decisions about their care. They followed the service policy and procedures when a patient could not give consent.
- 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.
- Sonographers completed training in relation to the Mental Capacity Act 1983 which formed part of their mandatory training.
- All service users received written information with a copy of the consent form to read prior to the planned scan appointment. This information included the risks involved with the procedure and explained referrals to other services if potential anomalies were found. Staff gained written consent from all women using the service prior to their scan. Service users had opportunities to ask staff questions before and after the baby scan.
- The service provided souvenir and keepsake baby imaging to women over the age of 16 years. Women aged 16 to 17 years were required to attend with a parent or guardian for consent purposes. The registered manager confirmed the booking information with women including their date of birth before their appointment and recorded information about parents and guardians on the scan consent form.
- Staff we spoke with understood their responsibilities in gaining consent before the baby scan took place and in relation to Gillick competence for patients aged under 18 years. However, staff told us that they did not often have bookings for women aged under 18 years.

Are diagnostic imaging services caring?

Good

We rated caring as **good.**

Compassionate care

- Staff cared for patients with compassion. Feedback from patients confirmed that staff treated them well and with kindness.
- Staff maintained service users' privacy and dignity at all times during their baby scan appointment. Staff carried out ultrasound scans in a private room which was warm to ensure women were comfortable for the duration of the appointment.
- We observed staff providing care to women and those accompanying them. Women were treated with compassion dignity and respect. Staff explained the scanning process and what to expect in a way that women understood.
- Staff were kind in their approach to women and those close to them but remained professional at all times. Women we spoke with praised the staff for their friendly professional approach.
- The service did not participate in the friends and family test, however they had their own patient feedback survey. Staff displayed feedback and comments on paper balloons on a waiting room wall display.
- We reviewed feedback from service users which was consistently positive. All of the feedback was extremely complimentary about the care they received. One patient wrote, "We would like to thank them for their professionalism and how lovely they were".
- Another service user wrote "Third visit and another perfect experience".
- Service users we spoke with told us that the service was recommended to them by others that had used the service.

Emotional support

- Staff provided emotional support to patients to minimise their distress.
- Staff prepared women attending scans at seven weeks for the possibility that if the dates are wrong a scan may not be possible. We observed staff preparing women

prior to their appointment and staff advised that they would be offered another scan in a few weeks and there would be no charge for this scan. Staff explained that a later scan would be booked at a later date.

- We observed a scan where a woman presented thinking she was seven weeks pregnant staff found the pregnancy was under seven weeks during the scan. The woman was visibly distressed and staff comforted her and gave reassurance that this happened from time to time that women presented too early. Staff answered questions and booked a later scan without charge. Staff explained if the scan was conducted too early the heart beat would not be visible and gently signposted the woman to her GP or named midwife if she had any bleeding or discomfort. However, this was not provided in a written format that women could read after leaving the building for reassurance.
- We saw feedback from service users praising staff for their professionalism and their kindness on breaking the news that an NHS scan where the sex of the baby had been incorrect. They felt supported by staff after they received this news.
- Staff we spoke with told us that women were not charged for scans when a potential baby death was found or where women presented too early and had a follow up scan. Staff told us that women had emotional distress and they did not feel requesting payment in these cases was appropriate.

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 actively included women and those close to them to have involvement in the scanning process. We observed staff providing care to women and those close to them, staff were open and invited any questions before and after the scan.
- The service had chairs in the scanning room so that those accompanying women could be involved in the scanning process so they were included in viewing the baby scan and could ask questions.
- Service users we spoke with told us that they had received enough information before and during their appointment. They also felt they had been given opportunities to ask questions from the start to the end of their appointment.
- Women had a choice of keepsake and souvenir images of their baby to take away. The registered manager was available to assist in this process if women had any questions or required guidance in this process.

Are diagnostic imaging services responsive?

Good

We rated responsive as **good.**

Service delivery to meet the needs of local people

- The service planned and provided services in a way that met the needs of local people. The service had suitable premises and facilities to meet the needs of their service users.
- The service only provided private keepsake baby scans and did not complete any imaging on behalf of the NHS or other private providers.
- The service reviewed the numbers of each baby scan type on a monthly basis to ensure they had the capacity to meet the needs of service users.
- The service actively sought feedback from service users and implemented improvements based upon this feedback. Records we reviewed show that service users had said they would like the option of their baby images saved on a USB stick. The service now offers baby images saved to a USB stick as a result of service user feedback.
- We spoke with the registered manager, who told us that feedback from women was important and informed improvements to the service provided.

Meeting people's individual needs

- The service took account of patients' individual needs.
- The service had a flexible approach to scan appointments to meet the needs of women. The service mainly offered appointments in the afternoons, evenings and on Saturdays mornings. The registered manager provided examples of how they had taken bookings in the mornings if women were unable to attend appointments during their normal opening times.
- The registered manager gave us examples of where appointments were offered outside of their normal

working hours. Records we reviewed showed that the service offered keepsake and souvenir scans during the day if a woman could not attend during their normal operating hours in the evenings and at weekends.
- The service could provide written information in foreign languages when a women's first language was not English. The registered manager told us that they asked women to request this service during their appointment booking.
- Staff gave us example of adaptions they had made for women with hearing impairments to ensure that women could see their face to lip read. Staff ensured that they changed position when talking to deaf service users to ensure they had face to face contact during these appointments.
- The waiting room had a designated area for prams and pushchairs, where women had small children accompanying them to their appointment.
- The service offered women a range of baby keepsake and souvenir options. A 'heartbeat bear' contained a recording of an unborn baby's heartbeat as a keepsake and were available in scanning packages from 23 weeks. Baby heartbeats were recorded for women if a heartbeat bear was included in their scan package.

Access and flow

- People could access the service when they needed it.
- Women referred themselves for keepsake, sexing and reassurance scans. The service provided information on their website about the price of the scanning packages. Staff provided information about prices with telephone bookings.
- The service performed 1,127 baby keepsake scans from October 2017 to September 2018. The service completed an average of 94 baby keepsake scans every month.
- Data provided by the service showed that seven women did not attend their booked appointment from October 2017 to September 2018.
- The service carried out seven scans without charge from October 2017 to September 2018. Women were not charged for scans when women attended for a follow up if their pregnancy was under seven weeks at the first scan or a baby death was detected.
- The service monitored waiting times for service users. Records we reviewed showed that the average waiting time for service users arriving to their appointment was an average of 15 minutes from October 2017 to October 2018. The service had set a target to reduce the waiting time to 10 minutes in the next reporting period.
- The service had a turnaround time between appointments of five minutes. The time allowed staff to ensure the equipment was cleaned and prepared for the next appointment.

Learning from complaints and concerns

- The service treated concerns and complaints seriously, investigated them and learned lessons from the results, and shared these with all staff.
- The service had an up-to-date complaints policy for staff to refer to in the event of a complaint. The policy set out the responsibilities of staff and set out the complaints process. In the event of a complaint an acknowledgement was sent within five working days. A full response was sent to the complainant within 20 working days with a caveat to extend this period if the investigation was complex, this was notified in writing.
- The service received five complaints from service users from October 2017 to October 2018. Records we reviewed showed that all of the complaints had been resolved by the service.
- We reviewed the complaints the service had received and the measures the service had taken to resolve them. We saw that the service managed complaints well and within the time set out within the local complaints policy.
- We saw that the service had withdrawn a scanning package provided in conjunction with a local photographic studio as a result of a complaint investigation.
- The registered manager told us that she shared information about complaints with staff verbally and provided updates to staff. Staff we spoke with confirmed this.

Are diagnostic imaging services well-led?

Requires improvement

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

Leadership

Good

Diagnostic imaging

- The registered manager generally had the right skills and abilities to run a service providing high-quality sustainable care.
- The registered manager had been in post since the service opened in 2015 and led the service. The registered manager understood their role and responsibilities, they had the skills and experience to manage the service.
- The registered manager communicated with staff well. We observed the registered manager providing verbal updates to staff before service users arrived for their appointments.
- The registered manager supported staff well and provided regular feedback staff about their performance during appraisal discussions. Staff we spoke with told us that they received updates from the registered manager during each shift they worked.

Vision and strategy

- The service had a vision for what it wanted to achieve and workable plans to turn it into action.
- The registered manager developed the service with the vision of providing affordable baby keepsake and souvenir baby images for women. The registered manager told us that this type of service was not available locally when the service opened and other services offering similar services were very expensive and offered diagnostic services rather than keepsakes.
- The vision for the service remained the same to provide affordable baby keepsakes to women. The service strategy was developed and underpinned by the vision and to ensure women were referred to appropriate services if any concerns were detected.
- The service monitored feedback from service users and audit data to make strategic changes to the service.

Culture

- The registered manager of the service promoted a positive culture that supported and valued staff, creating a sense of common purpose based on shared values.
- Staff we spoke with told us the registered manager was open and approachable. Staff praised their manager and felt supported to raise concerns and the registered manager was visible during opening hours.
- Staff we spoke with, felt proud to work for the service and they strived for excellence in the quality of service women received.
- We observed that staff worked well together. Staff had close working relationships and demonstrated a team approach to their work. Each member of staff took responsibility in the safety and quality of the service provided.

Governance

- Service quality was systematically improved and high standards of care were safeguarded by creating an environment for excellent clinical care to flourish.
- Due to the small size of the service the registered manager was solely responsible for the governance and oversight of the service. The registered manager compiled audit data monthly and this information was used within an annual report.
- The registered manager mostly had systems and processes in place to maintain oversight of the service. The service had an audit programme in place to provide assurance of the quality and safety. However, we found gaps in mandatory training completion assurance where staff completed training within the local NHS trust and inconsistencies in the mandatory training provision. This meant we were not assured that the service had systems in place to provide mandatory training for staff who were not employed by an NHS organisation.
- The registered manager used audit data and service user feedback to inform changes and to gain assurance of the quality and safety of the service. The registered manager generated yearly reports based upon audit data, appointment data including waiting times and appointment turnaround times and service user feedback to inform service improvement. However, the service did not have assurance systems in place for the quality of images produced.
- We reviewed the audit report generated in October 2018, which identified that service user waiting times were an average of 15 minutes. The report specifies an improvement to be made for the following year to reduce the average waiting time to 10 minutes.

Managing risks, issues and performance

- The service generally had systems to identify risks, plan to eliminate or reduce them, and cope with both the expected and unexpected.
- The registered manager mostly understood their responsibilities in relation to risk identification and action required to mitigate the identified risks. The

service recorded clinical, financial and reputational risks together in one document. However, the registered manager had not identified the mandatory training issues for staff who worked solely for the service as a risk.

- The service had a risk register in place with five risks identified with a risk rating. These risks included; risks to clients from services provided (ultrasound), environmental risks to clients and staff, clients and staff accessing the location, financial risk from competitors and reputation risks. We reviewed risk assessments which provided details of the identified risks and the mitigation in place to minimise the impact.
- We reviewed the risk associated with ultrasound scans and we saw that the service had implemented the recommendations set out by British Medical Ultrasound Society and staff worked to the code of practice set out the Society of Radiographers to minimise this risk.
- The service had one risk rated as medium to high, financial risks from competitors. This risk was mitigated by the high quality of service user experience and the values of affordable services. All of the other identified risks were rated as low risk which had actions in place to mitigate the impact of risks.

Managing information

- The service collected, analysed, managed and used information well to support all its activities, using secure electronic systems with security safeguards.
- The service had clear processes for managing information, images were kept for six months after the baby scan appointment and the service kept consent forms securely within a locked storeroom.
- The service compiled audit information to monitor the quality and safety of the service provided to women. This information was used to make improvements to the service in addition to feedback from service users.
- The service had processes in place to share information with service users GPs and the local NHS trust in the event of any concerns. The service had clear process in place to raise safeguarding concerns with the local authority safeguarding board and in neighbouring counties.

Engagement

- The service engaged well with patients, staff, the public and local organisations to plan and manage appropriate services, and collaborated with partner organisations effectively.
- Staff engaged well with service users. The service had a website which provided information to women about the service provided and prices of different scans or scanning packages. The service actively sought feedback from service users by means of a formal feedback form.
- The registered manager told us about service users that had returned with their babies to thank staff.
- The service had established processes in place to share information with other healthcare providers and local safeguarding boards.
- Staff received feedback about their performance every three months and records we reviewed confirmed this. The service gained annual feedback from staff by means of the staff survey. Record showed that all members of staff had engaged with this process.
- Staff we spoke with told us that they had regular contact with the registered manager and had regular verbal updates about the service.

Learning, continuous improvement and innovation

- The service was committed to improving services by learning from when things went well or wrong, promoting training, research and innovation.
- The registered manager monitored the quality and safety of the service through the monthly audit programme. The service identified and target areas for improvement, an example of this was the reduction in service user waiting times.
- The service took account of service user feedback and implemented changes as a result of this feedback. Service users told the service that they did not have equipment to view CD-ROM images. The registered manager introduced memory sticks to give service users a choice of the saved format of their baby images.

Outstanding practice and areas for improvement

Outstanding practice

- The service opened outside of their usual opening hours for women who could not attend during this time. This meant the service flexible to be inclusive to all women who wanted a baby keepsake scan.
- The service prepared women well, when attending for an early pregnancy scan at seven weeks that if the scan is completed early a heartbeat will not be seen. A later scan was offered free of charge a few weeks later where the scan was undertaken before seven weeks of pregnancy.

Areas for improvement

Action the provider MUST take to improve

- The service must ensure that systems and processes are in place to ensure all staff have access to annual mandatory training and they complete it.

Action the provider SHOULD take to improve

- The service should implement assurance process for the quality of baby keepsake images produced.

This section is primarily information for the provider

Requirement notices

Action we have told the provider to take

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

Regulated activity	Regulation
Diagnostic and screening procedures	Regulation 17 HSCA (RA) Regulations 2014 Good governance **Regulation 17 (1)(2)(b)(d)(i)**