Himom 4D Baby Bonding Studio

Quality Report

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Date of inspection visit: 22 January 2019
Date of publication: 13/03/2019

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?	Not sufficient evidence to rate
Are services caring?	Good
Are services responsive?	Good
Are services well-led?	Requires improvement

Summary of findings

Letter from the Chief Inspector of Hospitals

Himom 4D Baby Bonding Studio is operated by Dr Tariq Mahmood. The service carries out pregnancy baby ultrasound scans for souvenir videos or images, rather than for clinical purposes or as part of a pregnancy pathway of care. Facilities include one scanning room and reception area.

The service provides ultrasound baby imaging for non-diagnostic purposes. These are commonly known as 'keepsake' or 'baby souvenir' scans. They provide parents-to-be with images and/or recordings of their unborn baby as mementoes only.

We inspected this service using our comprehensive inspection methodology. We carried out a short notice announced inspection (we gave staff four days' notice that we were coming to inspect) on 22 January 2019.

To get to the heart of patients' experiences of care and treatment, we ask the same five questions of all services: are they safe, effective, caring, responsive to people's needs, and well-led? Where we have a legal duty to do so we rate services' performance against each key question as outstanding, good, requires improvement or inadequate.

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

The only service provided by this facility was ultrasound baby imaging for non-diagnostic purposes.

Services we rate

We rated it as **Good** overall.

We found areas of good practice:

- The provider had the right qualifications, skills, training and experience to keep people safe from avoidable harm and to provide the right care and treatment.
- Staff cared for women with compassion, kindness and respect. They involved women and those close to them in decisions about their care and treatment.
- Current evidence-based guidance and good practice standards were used to inform the delivery of care and treatment. The provider demonstrated understanding of the guidance and legislation that affected their practice.
- The service had a vision, where the delivery of quality care was the top priority, and the provider worked to achieve it.
- The provider promoted a positive culture.
- The provider monitored scan image quality and gender determination outcomes.
- Women could access services and appointments in a way and time that suited them.
- The provider understood how and when to assess whether a woman had the capacity to make decisions about their care.
- Services provided reflected the needs of the population served and individual needs were taken into account.

We found areas of practice that require improvement:

- We were not assured that sufficient governance arrangements were in place to ensure high standards of care were maintained. There was no system in place to manage and monitor incidents, complaints and risks.
- There was no system in place to identify training needs and monitor compliance.

Summary of findings

- There was no checklist in place to show when the environment and equipment was cleaned, or that equipment was checked regularly to ensure it was fit for purpose.
- The provider did not give women a written record of their findings if they found a suspected concern and needed to refer them to NHS services.
- There was limited engagement with women, those close to them and the public, and we did not find any evidence of change because of comments or complaints received.

Following this inspection, we told the provider that it must take some actions to comply with the regulations and that it should make other improvements, even though a regulation had not been breached, to help the service improve. We also issued the provider with **one** requirement notice that affected Himom 4D Baby Bonding Studio. Details are at the end of the report.

Amanda Stanford
Deputy Chief Inspector of Hospitals (Central)

Summary of findings

Our judgements about each of the main services

Service	Rating	Summary of each main service
Diagnostic imaging	Good 	We rated this service as good because it was safe, effective, caring and responsive to people's needs. However, it requires improvement for being well-led.

Summary of findings

Contents

Good

Services we looked at
Diagnostic imaging.

Summary of this inspection

Background to Himom 4D Baby Bonding Studio

Himom 4D Baby Bonding Studio is operated by Dr Tariq Mahmood. The service opened in September 2012. It is a private service in Kidderminster, Worcestershire, and primarily serves the communities of the West Midlands area. It also accepts women from outside this area.

The facility provides pregnancy ultrasound scanning services for non-diagnostic purposes. This means the ultrasound is not performed for any clinical reason, such as screening for fetal abnormalities, but to provide the parents-to-be with images and/or recordings of their unborn baby as keepsakes only. The service provides:

- Gender determination scans.
- 2D/3D/4D baby scans.

Dr Tariq Mahmood registered as a provider with the Care Quality Commission (CQC) in January 2013. They were solely responsible for the service.

The facility offers services to self-pay funded women.

Himom 4D Baby Bonding Studio has been inspected once by the CQC, in August 2013. At the last inspection, we did not have a legal duty to rate the service. We did issue the provider one compliance action in relation to a regulation that was not being met, and where they needed to make improvements.

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 Julie Fraser, Inspection Manager, and Bernadette Hanney, Head of Hospital Inspection.

Information about Himom 4D Baby Bonding Studio

The service is located on the ground floor of a converted listed building. Facilities include one scan room, a reception and waiting area, and a further room for women and those accompanying them to sit in privacy, if needed. The service is registered to provide the following regulated activities:

- Diagnostic and screening procedures.

During the inspection, we visited all areas of the service. We interviewed the provider, spoke with three women and two partners, and reviewed 78 consent forms.

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 has been inspected once, which took place in August 2013. We found the service was not meeting one of the standards of quality and safety it was inspected against. We told the provider it needed to make improvements in relation to one regulation that was not being met.

Activity (January to December 2018):

- In the reporting period January to December 2018, there were 408 scanning procedures performed at the service; of these 100% were privately funded.

There was one sonographer at the service, who was the provider. When we carried out the inspection, the service also employed a part-time receptionist. However, within a week of our site visit, we were told they had left the service.

Track record on safety (January to December 2018):

- Zero never events
- Zero clinical incidents

Summary of this inspection

- Zero serious injuries
- Zero complaints

Detailed findings from this inspection

Overview of ratings

Our ratings for this location are:

	Safe	Effective	Caring	Responsive	Well-led	Overall
Diagnostic imaging	Good	Not rated	Good	Good	Requires improvement	Good
Overall	Good	Not rated	Good	Good	Requires improvement	Good

Notes

We do not currently rate the effectiveness of diagnostic imaging services.

Good

Diagnostic imaging

Safe	Good
Effective	Not sufficient evidence to rate
Caring	Good
Responsive	Good
Well-led	Requires improvement

Are diagnostic imaging services safe?

Good

We rated it as **good.**

Mandatory training

- **While the provider had completed mandatory training in key skills, we were not assured there was a system in place to identify training needs and monitor compliance.**
- The provider had completed mandatory training with another provider who they regularly worked for. As of January 2019, they had completed infection prevention and control, safety and hygiene, information governance, first aid, and safeguarding adults and children training. However, there was no evidence they had completed training in other key skills, such as fire safety, and equality and diversity. Following our inspection, we saw the provider had completed fire safety training. Furthermore, other than safeguarding training completed in 2013 and 2014, the part-time receptionist had not undertaken any other training. Nor had their training needs been identified. This meant we were not assured the provider had identified what training in key skills was needed. Nor did they have a system in place to ensure staff were up to date with mandatory training.
- Training was provided via e-learning modules.

Safeguarding

- **Staff understood how to protect women who used the service and those who accompanied them from abuse and worked well with other agencies to do so.** The provider had completed training on how to recognise and report abuse and they knew how to apply it. However, there was no safeguarding policy in place.
- The provider had a good understanding of their responsibilities with regards to recognising and reporting potential abuse. They were able to describe the steps they would take if they were concerned about the potential abuse of women who used the service or visitors. However, the provider did not have a safeguarding policy in place. This meant we were not assured the receptionist would know what action to take if they were concerned about potential abuse. We were told the receptionist was never on-site without the provider being present.
- While there was no safeguarding policy in place, the provider had a folder that contained details of the local authority safeguarding teams. They would contact them directly if they had any concerns and gave us an example of when they had done so.
- The provider had up-to-date training in safeguarding adults and children level two. However, we found the part-time receptionist had last completed safeguarding adults and children training at level one in November 2013 and June 2014 respectively. This was not in line with national guidance, which states that refresher training should be provided three-yearly (Intercollegiate Document, Adult Safeguarding: Roles and Competencies for Health Care Staff, August 2018; Intercollegiate Document, safeguarding children and young people: roles and competences for health care staff, March 2014).

Good

Diagnostic imaging

- The service did not provide pregnancy ultrasound scans to women under the age of 18 years. However, children could attend ultrasound scan appointments with their mothers.
- There had been no safeguarding concerns reported to CQC in the reporting period from January to December 2018.
- Safety was promoted in recruitment procedures and employment checks. Staff had Disclosure and Barring Service (DBS) checks carried out at the level appropriate to their role. We saw that the DBS check for the provider was carried out in December 2015, and for the receptionist in October 2013. A DBS check has no official expiry date, although it is considered best practice to repeat it every three years. The provider told us they had asked another provider who they regularly worked for, to submit an enhanced DBS application for them.

Cleanliness, infection control and hygiene

- **Infection risk was generally controlled well. The equipment and premises were clean. However, there was no checklist in place to show when the environment and equipment was cleaned. Nor was there an infection prevention and control policy in place.**
- We found all areas of the service were visibly clean and tidy. A service level agreement was in place between the service and an external cleaning provider. We were told the premises were cleaned once or twice a week, depending when women attended. However, there was no cleaning checklist in place to evidence what areas were cleaned and when. Nor was there an infection prevention and control policy in place. This meant we were not assured there were processes in place to ensure the premises and equipment were cleaned as required.
- Best practice guidance was followed for the routine disinfection of ultrasound equipment (European Society of Radiology Ultrasound Working Group, Infection prevention and control in ultrasound – best practice recommendations from the European Society of Radiology Ultrasound Working Group, 2017). The provider decontaminated the ultrasound transducer with disinfectant wipes between each woman and at the end of each day. The transducer was the only part of the ultrasound equipment that was in contact with women.
- There were suitable handwashing facilities for the size and scope of the service. Hand sanitising gel dispensers were available in the scanning room and reception area for staff, women and visitors to use. Hand washing facilities were available in the toilet. The provider told us they cleaned their hands with sanitising gel before and after each contact with women who used the service.
- Flooring throughout the service appeared well maintained and visibly clean. The scanning room and reception area were carpeted. However, as no clinical procedures were carried out by the service there was very little risk of infection from blood or other bodily fluid spillages.
- Disposable paper towel was used to cover the examination couch. This was changed between each woman.
- The provider's immunisation history for the prevention of transmissible diseases was available and up to date.
- From January to December 2018, there had been no instances of healthcare acquired infections (Source: Routine Provider Information Request).

Environment and equipment

- **The premises and equipment were suitable for purpose and were well looked after, except for the first aid kit and fire extinguisher. The provider took immediate action to ensure these items of equipment were fit for purpose.**
- A first aid kit was available but we found it had an expiry date of October 2015. Similarly, while a fire extinguisher was accessible, the provider was unable to evidence when it had last been serviced. This meant we were not assured there was a system in place to ensure essential equipment was fit for purpose. We raised these concerns with the provider who took immediate action to address them. Within two days of our inspection visit we saw that a replacement fire extinguisher had been installed and commissioned, and the first aid kit had been replaced.

Good

Diagnostic imaging

- The manufacturer provided the maintenance and servicing of the ultrasound machine. The manufacturer also monitored the ultrasound machine's performance remotely, to ensure it was functioning effectively and optimal levels of output were maintained.
- The provider had received training on how to use the ultrasound machine from the manufacturer. They could also contact them for advice and support when needed.
- The portable electrical equipment we saw, which included the computer, telephone and heaters, were last safety tested in May 2017. This was in line with national guidance (Health and Safety Executive, Maintaining portable electric equipment in low-risk environments, September 2013).
- The scanning room had one wall-mounted slave monitor, which projected the images from the ultrasound machine. This was in line with recommendations, as it enabled women and their families to view their baby scan more easily.
- Waste was handled and disposed of appropriately. The service did not have any clinical waste.

Assessing and responding to patient risk

- **Arrangements were in place to assess and manage risks to women.**
- The service provided pregnancy ultrasound scans for keepsake purposes only. This meant no diagnostic screening was performed for clinical purposes or as part of maternity pathways of care. The terms and conditions for the service clearly advised women that their ultrasound scan was not a substitute for the NHS scans offered during pregnancy and that they should still attend these. Women were made aware of this prior to their appointment and were asked to sign a contract to confirm that they had read and understood the terms and conditions before any scan was undertaken.
- The provider had clear processes in place to escalate unexpected or significant findings identified during ultrasound scans, such as a possible concern. We saw protocols were in place for referral to NHS services. The provider told us they had not needed to refer any women to NHS services because of potential concerns found. However, they could clearly describe what they would do if needed.
- The provider told us they refused to scan any woman who requested a reassurance scan in the early stages of their pregnancy because they had spotting (light bleeding) or were in pain. Instead, they would advise the woman to seek immediate advice from their GP, midwife or early pregnancy unit.
- Women were advised to bring their NHS pregnancy records to their appointment. This meant the provider had access to their obstetric and medical history, if needed. It also meant they had the contact details for the woman's maternity care provider if an unexpected or significant finding was identified.
- The provider told us they would telephone 999 for urgent support if an emergency situation arose on the premises.
- The provider used the 'Paused and Checked' checklist devised by the British Medical Ultrasound Society (BMUS) and Society and College of Radiographers. This was displayed in the scanning room as a reminder for them to carry out these checks.
- The service's website contained a link to the BMUS safety statement on souvenir scanning.
- The service accepted women who were physically well and could transfer themselves to the couch with little support. The service did not offer emergency tests or treatment.

Staffing

- **The service had enough staff to keep people safe from avoidable harm and abuse, and to provide the right care and treatment.**
- Only the provider performed pregnancy ultrasound scans at the service. They were supported by a part-time receptionist. The provider was always on site when women and visitors attended the service.
- There were no staff vacancies at the time of our inspection. However, within a week of our site visit we

were told the receptionist had left the service. The provider told us they planned to recruit to this vacancy. The service did not use any bank, agency or locum staff.

Records

- **Staff kept minimal records of women's care. The records kept were clear, up to date and easily available to staff providing care. However, the provider did not give women a written record of their findings if they found a suspected concern and needed to refer them to NHS services.**
- The only paper records used and stored by the service were women's consent forms. The consent forms detailed the terms and conditions of the service, which women were asked to read, sign and date before any ultrasound scan was undertaken. The scan forms also included their gestation (the number of weeks of their pregnancy). We reviewed 78 consent forms and found they were completed.
- At the time of our inspection, the provider told us they would not provide women with written information if they suspected a concern and needed to refer them to NHS services. They told us they would contact the relevant healthcare professional and advise them over the phone of their concerns. However, this meant there was a potential risk that the person they spoke to may not be available when the woman went for review, and they may not have handed over the provider's suspected concerns to the relevant staff.
- The consent forms were stored securely in a locked cupboard. This prevented unauthorised people from accessing them.

Medicines

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

Incidents

- **The provider understood their responsibility to report, investigate and learn from incidents. However, there was no system in place to manage incidents. When things went wrong, staff apologised and gave women honest information and suitable support.**
- There was no system in place to manage incidents. The provider did not have a policy for managing incidents, nor did they keep a record of incidents reported. Due to the small size of the service, the provider told us they dealt with incidents as soon as they occurred. They gave us an example of one incident, where the power supply had failed. The provider told us they contacted those women who were booked to attend, apologised, and rearranged their appointments.
- From January to December 2018, the provider reported no never events or serious injuries (Source: Routine Provider Information Request). Never events are serious incidents that are entirely preventable as guidance, or safety recommendations providing strong systemic protective barriers, are available at a national level, and should have been implemented by all healthcare providers.
- The provider told us they had not had any incidents occur in the service for at least 12 months.
- The provider had some understanding of the duty of candour and told us they would always be open and honest with women if anything went wrong. The duty of candour is a regulatory duty that relates to openness and transparency and requires providers of health and social care services to notify patients (or other relevant persons) of certain 'notifiable safety incidents' and provide reasonable support to that person, under Regulation 20 of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014. The provider had not had any incidents that met the threshold for implementing the duty of candour.
- The provider was aware of their responsibility to report any notifiable incidents to the Care Quality Commission (CQC).

Are diagnostic imaging services effective?

Not sufficient evidence to rate

We do not currently rate the effectiveness of diagnostic imaging services.

Evidence-based care and treatment

Good

Diagnostic imaging

- **Care and treatment provided was based on national guidance and good practice standards.**
- The service followed the ALARA (as low as reasonably achievable) principles. This was in line with national guidance (Society and College of Radiographers (SCoR) and British Medical Ultrasound Society (BMUS), Guidelines For Professional Ultrasound Practice, December 2018). Where possible, the provider completed all ultrasound scans within 10 minutes to help reduce ultrasound patient dose.
- The provider adhered to the 'Paused and Checked' checklist, which was designed as a ready reminder of the checks that need to be made when any ultrasound examination is undertaken. This was in line with national standards (Society and College of Radiographers (SCoR) and British Medical Ultrasound Society (BMUS), Guidelines For Professional Ultrasound Practice, December 2018).
- There were protocols in place for the referral of women to other services in the event that unexpected or significant findings were found during ultrasound scans, such as a possible concern.
- An appointments protocol was in place, which detailed the procedure for booking women an appointment. This included explaining to women that the ultrasound scans performed at the service were not a replacement for those offered as part of their NHS pregnancy pathway.
- The service was inclusive to all pregnant women and we saw no evidence of any discrimination, including on the grounds of age, disability, pregnancy and maternity status, race, religion or belief, and sexual orientation, when making care and treatment decisions.

Nutrition and hydration

- Women were told they could eat and drink as normal before their scan. They were also advised to hydrate their body by drinking two extra glasses of water a day, three to four days before their appointment, because this could help improve the quality of the ultrasound image. This information was told to women prior to their appointment and was included in the 'frequently asked questions' on the service's website.
- Due to the nature of the service and the limited amount of time women spent there, food and drink was not routinely offered. However, hot and cold drinks could be provided if needed.

Patient outcomes

- **The provider monitored scan image quality and gender determination outcomes.**
- From January to December 2018, the provider performed 408 baby keepsake scans. During this period, they did not refer any women to NHS services because of suspected concerns.
- The provider told us they reviewed the quality of their scan images. If they were not happy with the quality, they would contact the woman and invite her for a free scan.
- From January to December 2018, the provider had performed eight rescans because of the position of the baby.
- Women were offered a free scan if the provider told them the incorrect gender of their baby. The provider told us no women had reported that the gender of their baby was wrong in the last 12 months.
- The provider participated in sonographer peer review audits. These were undertaken at the independent pregnancy ultrasound service where they also worked. This meant their ultrasound observations and report quality were reviewed by a peer. This was in line with professional guidance, which recommends peer review audits are completed using the ultrasound image and written report (Society and College of Radiographers (SCoR) and British Medical Ultrasound Society (BMUS), Guidelines For Professional Ultrasound Practice, December 2018). The peer review audit assessed their activity, technical knowledge and communication skills, such as their scan room hygiene, accuracy of gender determination, knowledge of ALARA principles and their ability to answer questions and concerns. They were rated from one (needs improvement) to five (good). We saw the provider was rated as three (acceptable) or five (good) for all measures.

Competent staff

Good

Diagnostic imaging

- **Staff had the skills, competence and experience needed for their roles.**
- We reviewed the staff personnel files for the provider and receptionist. They contained evidence of employment history, identification, disclosure and barring service (DBS) checks, and two employment references. This was an improvement from our last inspection in August 2013, when we found the provider had not undertaken appropriate checks prior to staff taking up employment.
- The provider was skilled, competent and experienced to perform the pregnancy ultrasound scans they provided. They also performed similar ultrasound scans for privately funded women at another independent pregnancy ultrasound provider. They had completed training for the ultrasound equipment used.
- The provider was a trained radiologist and was registered with the General Medical Council (GMC) but not licensed to practice. This registration status is applicable to doctors who are not practising medicine but want to keep their GMC registration. This allows them to show employers and others that they remain in good standing with the GMC. They were also a member of the BMUS.
- The provider participated in continuing professional development. They had recently undertaken a course provided by a local university and had been awarded a postgraduate certificate in medical ultrasound in January 2019.

Multidisciplinary working

- The provider was the sole employee of the service. However, they worked together with the local authority safeguarding teams, GPs and NHS healthcare professionals to benefit women who used the service, when indicated.

Seven-day services

- The service did not provide pregnancy ultrasound scanning for any clinical reason, such as scans offered as part of the NHS antenatal pathway. This meant services did not need to be delivered seven days a week to be effective.
- The service did not open every day, but staff worked in a flexible way to meet the needs of women. All scans performed were planned, with appointments arranged in advance.

Health promotion

- The service provided clear written information that the scanning services they provided were not a substitute for antenatal care.

Consent and Mental Capacity Act

- **The provider understood how and when to assess whether a woman had the capacity to make decisions about their care. They were aware of the importance of gaining consent before performing any ultrasound scan.**
- Women were supported to make informed decisions about pregnancy ultrasound scans for souvenir purposes. The service's website contained a link to national guidance on the use of ultrasound for souvenir baby scanning (European Committee of Medical Ultrasound Safety (ECMUS), Statement on Souvenir Scanning, endorsed by BMUS Council October 2007).
- Consent to care and treatment was sought in line with legislation and guidance. Women were asked to read and sign the terms and conditions of the service before any ultrasound scan was undertaken. The terms and conditions clearly stated that the ultrasound scan was for souvenir purposes only. They also clearly stated that they were not a substitute for the scans offered by the NHS, nor was the sonographer able to offer medical or diagnostic advice. The provider checked that women understood the terms and conditions and scan limitations, before they performed any pregnancy ultrasound souvenir scans. We did note that the terms and conditions stated the service offered ultrasound scans on the understanding that they were receiving antenatal care and had had one normal scan. However, we saw the provider had used these terms and conditions to consent women from six weeks gestation, who would not yet have had an NHS scan.

Good

Diagnostic imaging

- The provider understood how and when to assess whether a woman had the capacity to make decisions about their care. They told us they had not had any women who lacked capacity request their services.
- The provider had up to date training in the Mental Capacity Act (2005) and Deprivation of Liberty Safeguards.

Are diagnostic imaging services caring?

Good

We rated it as **good.**

Compassionate care

- **Staff cared for women with compassion. Feedback from women confirmed that staff treated them well and with kindness.**
- Women's privacy and dignity was maintained during their ultrasound scan. Women with spoke with corroborated this. The provider carried out all ultrasound scans in a private room. This meant that women could speak to them without being overheard.
- We spoke with three women and two partners about various aspects of their care. Without exception, feedback was positive about their experience, and the kindness and care they received. One woman told us they "would give it top marks in everything".
- The provider asked women to leave feedback about their care and a rating of their experience on the service's social media page. The average rating for the service was 4.5 out of five. However, it should be noted that this was based on ratings posted from July 2013 to December 2018. Most of the feedback was complimentary about the service. One woman wrote; "Excellent service from start to finish". Another wrote; "I will definitely be recommending you to anyone who is looking for a private scan".

Emotional support

- **Staff provided emotional support to women to minimise their distress.**
- The provider was aware that women attending the service were often feeling nervous and anxious, and they provided additional reassurance and support to these women.
- The provider told us they had not had to refer any woman to other services because they had identified a potential concern. If they did identify a potential concern they would communicate this sensitively and would arrange appropriate follow up care.
- Women were advised to have their keepsake pregnancy ultrasound scan once they had had their anomaly scan, which is part of the NHS maternity pathway and its primary purpose is to ensure the baby is growing well without abnormalities. This reduced the risk of the provider identifying any unexpected concern. However, the provider told us they received an increasing number of requests for early scans from women who were extremely anxious and wanted reassurance that they were pregnant. The provider told us they would counsel these women and would only perform an early reassurance scan if they had no symptoms of possible miscarriage, such as bleeding and abdominal pain. If they did report any symptoms, the provider would advise them to contact their GP, midwife or early pregnancy unit for advice.
- Women were provided with written information explaining the procedure prior to their appointment.

Understanding and involvement of patients and those close to them

- **Staff involved women and those close to them in decisions about their care and treatment.**
- The provider communicated with women and those accompanying them so that they understood their care and treatment. The women and partners we spoke with told us they felt fully involved in their care and had received the information they needed to understand their scan procedure. One woman told us they were; "Happy with the way [the provider] communicated. They explained everything in a way they could understand". Another woman felt the provider; "Went above and beyond with their explanation and the time they spent with them".

Good

Diagnostic imaging

- The women and partners we spoke with felt they were fully involved in their care and had been given the opportunity to ask questions throughout their appointment.
- Women were encouraged to make their experience a family occasion. Partners, children, other relatives and/or friends were welcome to attend the appointment with the woman.
- There were appropriate discussions about the cost of keepsake pregnancy scans. Women were advised of the cost of their planned scan when they booked their appointment. This information was also available on the service's website.

Are diagnostic imaging services responsive?

Good

We rated it as **good.**

Service delivery to meet the needs of local people

- **The services provided reflected the needs of the population served. The service generally had suitable premises and facilities to meet the needs of women.**
- The service only provided private keepsake baby scans and did not complete any ultrasound imaging on behalf of the NHS or other private providers. The service offered gender determination scans, and 2D, 3D and/or 4D baby images. The provider told us they received an increasing number of requests for early reassurance scans, which they would perform if the woman was well and had no symptoms of possible miscarriage.
- The service was located on the ground floor of a converted listed building, and was accessible to women and those accompanying them. The scanning room had an adjustable couch, which was used to assist and support women with limited mobility.
- The facilities and premises were generally appropriate for the services delivered. There was a comfortable seating area and toilet facilities for women and those accompanying them. A room was also available for women and those accompanying them to sit in privacy if needed, such as when a potential concern was found. However, we did find the premises were cold. The provider told us that the heating system was inefficient and they had bought portable heaters to try and overcome this issue. These were switched on before women arrived, to ensure the waiting area and scanning room were at a comfortable temperature when they attended their appointment. One woman we spoke with however, did comment that the room was cold. Furthermore, we found none of the magazines in the waiting area were current, and dated back as far as 2013.
- Women were provided with appropriate information about pricing and scan options before their appointment. The service offered several scan packages, which were clearly detailed on the service's website and information leaflet.
- Women were given relevant information about their ultrasound scan when they booked their appointment, such as whether they needed a full bladder and when was the best gestation for their scan. This information was also included in the 'frequently asked questions' on the service's website.
- The provider was flexible. Appointments could be arranged during the evenings and on Sundays if requested.
- There were no car parking facilities at the service. However, it was located close to public car parks, which were all within a short walking distance.

Meeting people's individual needs

- **The service generally took account of individual needs.**
- The appointment schedule allowed women sufficient time to ask questions before, during and after their ultrasound scan. Women and partners we spoke with corroborated this.
- Women received written information to read and sign prior to their ultrasound scan appointment. Copies of the terms and conditions and other key information was also available on the service's website. However, at the time of our inspection this information was only available in English.

Good

Diagnostic imaging

- At the time of our inspection, there was not a translation service in place that could be used during an appointment for non-English speaking women. The provider told us that non-English speaking women usually attended their appointment with a family member or friend, who could translate for them. However, the use of relatives and/or friends as interpreters is discouraged and not considered best practice. Following our inspection, the provider told us they had engaged the services of a translation and interpreter provider.
- All pregnancy ultrasound scans were undertaken in a private clinic room with lots of space for additional relatives, friends or carers to accompany the woman.

Access and flow

- **Women could access the service when they wanted it.**
- Women referred themselves for baby keepsake, gender determination and reassurance scans.
- At the time of our inspection, there was no waiting list or backlog for appointments. From January to December 2018, the service performed 408 baby keepsake scans. Data provided by the service showed that no scans were cancelled or delayed for non-clinical reasons during this period.
- Women were offered a choice of appointment. Women could book an appointment via the service's website, phone, text message or social media web page. The online booking system enabled women to book an appointment from 12pm to either 4.30pm or 5.30pm, depending on the day. However, the provider told us they were flexible and could provide appointments outside of these hours, and during the evenings and Sundays if requested. Appointments were not available on a Saturday because the provider worked at another independent pregnancy ultrasound scanning service on this day.
- There was no waiting time for scan results. Women were given a CD (compact disc) and/or DVD (digital video disc) of their keepsake baby images at the end of their appointment.

Learning from complaints and concerns

- **While concerns and complaints were treated seriously, investigated and measures taken to resolve them, there was no system in place to monitor complaints received. Nor was there a complaints policy in place.**
- The provider did not have a complaints policy in place. They told us they would respond to complaints within five working days of receipt.
- The provider did not have a system in place to monitor complaints, such as the date they received a complaint, the nature of the complaint, the measures they had taken to resolve the complaint, and the time it took them to respond and resolve it. The provider told us that most complaints were either because women were unable to clearly see the gender of their baby or they did not like the images. If the provider was unable to confirm their baby's gender or they got it wrong, they would offer the woman a free scan. Similarly, if they were unable to show them their baby's face because of position, they would also offer a free scan appointment.
- Information on how to make a complaint was publicly displayed in the waiting area and scanning room. This confirmed that complaints would be responded to within five working days. Contact details for the General Medical Council and Citizens Advice Bureau were also provided.
- From January to December 2018, the service reported no formal written complaints. Two women had posted negative feedback on the service's social media page, which we saw the provider had responded to. One of the reviews was in regard to the premises and the second was because the woman had been unable to see the gender of her baby, but had been told what it was by the provider. The provider had offered the woman a free scan if the gender was incorrect.

Are diagnostic imaging services well-led?

Requires improvement

We rated it as **requires improvement.**

Leadership

- **The provider had the right skills, knowledge and experience to run the service.**
- The provider led the service. They were solely responsible for it and carried out all activities related to it. They had worked for many years within the field of pregnancy ultrasound scanning for souvenir purposes. They were the only person who carried out ultrasound scans at the service.

Vision and strategy

- **The service had a vision, where the delivery of quality care was the top priority, and the provider worked to achieve it.**
- The vision for the service was to; "Provide easily accessible, high-quality 2D/3D/4D imaging using ultrasound technology in a caring and professional manner, in a homely and comfortable environment".
- The provider recognised that their current premises were not ideal, as the building was old and could not be easily altered because it was a listed building. They told us they were hoping to relocate the service to more suitable premises, but we were not given any timeframe for when they hoped to do this.

Culture

- **The provider promoted a positive culture.**
- The provider was welcoming, friendly and helpful. It was evident that they cared about the service they provided and tried to get the best possible images and make the experience as happy and positive as possible.
- The provider was aware of the duty of candour regulation but had not had any incidents that met the threshold for implementing the duty of candour.
- During and after our inspection, we informed the provider that there were areas of the service that needed improving. They responded positively to our feedback, demonstrating an open culture of improvement.

Governance

- **We were not assured that sufficient governance arrangements were in place to ensure high standards of care were maintained.**
- During our inspection, we found the provider did not have a checklist in place to assure themselves that the service was cleaned regularly and in line with infection prevention and control standards. Nor did they have a system in place to assure themselves that all equipment was fit for purpose. For example, we found the first aid kit expired in October 2015. This meant it had probably never been checked by the provider. Furthermore, there was no evidence that the fire extinguisher had been serviced. While the provider took immediate action to rectify these concerns, we were not assured they had governance systems in place to ensure these safety checks were not overlooked again.
- Similarly, we were not assured the provider had identified what training in key skills they needed. Nor did they have a system in place to ensure they and their staff were up to date with training. For example, they completed fire safety training when we asked to see evidence that they had done it.
- The terms and conditions were not appropriate for women who attended the service for early reassurance scans. The provider did not seem to have oversight of this until we raised it as a concern on inspection.
- There was no system in place to show how the service managed incidents and complaints, such as a policy and/or record of incidents that had occurred, and complaints received.
- Due to the small size of the service, the provider told us they did not have any policies in place. There was however, a protocol in place for the referral of women with suspected concerns to NHS services, and for the booking of appointments.
- The provider had indemnity insurance in place.

Managing risks, issues and performance

- **We were not assured that effective systems were in place to identify, reduce and eliminate risks, and to cope with both the expected and unexpected.**
- While the provider demonstrated some understanding of the potential risks within their service, at the time of our inspection they were unable to evidence any risk assessments they had carried out, nor was there a risk register in place. This meant we were not assured they

had identified risks within their service or that they had acted to minimise those risks. Following our inspection, the provider demonstrated they had undertaken a fire risk assessment. However, no other risk assessments were provided, such as an environmental risk assessment or the collapse of a woman or visitor.

Managing information

- **The service collected, managed and used information well to support its activities, using electronic systems with security safeguards.**
- There was a system in place to ensure women were provided with the terms and conditions of the service being provided to them, and the amount and method of payment of fees. The terms and conditions were available on the service's website and were given to women to read and sign before any scan was performed. They clearly stated that the full price of the scan must be paid before the scan was undertaken.
- Women's records and scan images were easily accessible and were kept secure. Paper records were stored in a locked cupboard. Electronic systems were password protected.
- The provider told us they transferred all scan images onto a CD monthly or when 30 per cent of data storage had been used and archived them. They then deleted the scan images from the ultrasound machine. The archived CD's were stored securely for up to three years.
- The provider had completed information governance training.
- The provider was registered with the Information Commissioner's Office (ICO), which was in line with The Data Protection (Charges and Information) Regulations (2018). The ICO is the UK's independent authority set up to uphold information rights.

Engagement

- **There was limited engagement with women and the public and we did not find any evidence of change because of comments or complaints received.**
- The provider did not use any customer surveys to gather feedback on the services they provided. Nor did they ask women for suggestions on how they could improve.
- The provider asked women to post feedback about the service on their social media web page. We reviewed those made in 2018 and found only six women had either left a review or posted a comment. While the provider told us, they had 10 reviews in 2018.
- We were not given any examples of improvements that had been made to the service because of comments or complaints received.
- The provider told us they did not market their services but relied on 'word of mouth' referrals.

Learning, continuous improvement and innovation

- The service did not undertake any continuous improvement or innovation. The provider did however, undertake continuing professional development activities and had recently completed a postgraduate course in medical ultrasound.
- The provider took immediate action to address some of the concerns we raised during our inspection. For example, they replaced the fire extinguisher and first aid kit, and carried out a fire risk assessment. They also completed training in fire safety awareness and the Mental Capacity Act and Deprivation of Liberty Safeguards.

Outstanding practice and areas for improvement

Areas for improvement

Action the provider MUST take to improve

- The provider must take prompt action to address a number of concerns identified during the inspection in relation to the governance and risk management of the service. They must ensure a system is in place to monitor and manage incidents, complaints and risks. The terms and conditions must be appropriate to all women who attend the service. They must ensure written policies are in place to cover the management arrangements for complaints, incidents, risk, safeguarding adults and children, and infection prevention and control. Furthermore, they must have a mandatory training programme in place and a system to ensure mandatory training is completed when required. Regulation 17 Good governance (1) (2)(a)(b)(d).

Action the provider SHOULD take to improve

- The provider should consider how they gather feedback from women in order to improve the quality of services provided.
- The provider should ensure there are translation services available for staff and women to use.
- The provider should ensure women who are referred because of suspected concerns to NHS services, are given a written record of the provider's scan findings.
- The provider should have a cleaning checklist in place to assure themselves that the environment and equipment is cleaned as required.

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 We were not assured that effective systems were in place to identify, reduce and eliminate risks. Similarly, we were not assured that sufficient governance arrangements were in place to ensure high standards of care were maintained.