Babyface4d

Quality Report

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

Ratings

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

Summary of findings

Letter from the Chief Inspector of Hospitals

Babyface4d is operated by Pregnancy Ultrasound ltd. The service is located in Bromsgrove and provides diagnostic pregnancy ultrasound scans to privately funded women across Worcestershire and its surrounding areas. The service operates a satellite clinic in Chelmsley Wood, Birmingham. We did not inspect the satellite service.

We inspected this service using our comprehensive inspection methodology. We undertook a short-notice announced inspection on 12 February 2019. We gave one weeks' notice of our inspection to ensure the availability of the registered manager and clinics.

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

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

Services we rate

We have not previously inspected. At this inspection in February 2019 we rated the service as **Requires improvement** overall.

We found areas of practice that required 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 monitor the quality of diagnostic reports, and no peer reviews or audits were carried out. Incidents, complaints and risks were not monitored, and there were limited policies and procedures in place.
- Not all infection risks were controlled well. Hand hygiene was not carried out in line with national guidance.
- While the registered manager had the skills, knowledge, and experience to conduct ultrasound scans, they had not establishedsuitable and effective policies and procedures to fulfil the requirements of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014 (Part 3). We were not assured that the provider could keep people safe from avoidable harm at all times.
- There was no system in place to identify training needs and monitor compliance to training.
- While the registered manager understood the need to protect people from abuse, and had completed safeguarding adults and children training, the receptionist had not received any training in safeguarding adults or children.
- The registered manager did not give women a written record of their findings if they found a suspected concern and needed to refer them to NHS services.
- Informed consent was not appropriately gained from women who did not have English as their first language.
- There was limited engagement with women, those close to them and the public, and we found limited evidence of changes made following comments or feedback received.
- The registered manager did not carry out peer reviews to ensure the quality of its work.
- Although services provided reflected the needs of the population served, not all individual needs were taken into account. There was no translation service or chaperone service available to women.

We found areas of good practice

- Staff cared for women with compassion, kindness and respect. They involved women and those close to them in decisions about their care and treatment.
- The registered manager promoted a positive culture.

Summary of findings

- The registered manager checked the clarity of scan images for baby keepsakes and offered free rescans if the image quality was poor, or if the baby's face could not be seen clearly.
- Women could access services and appointments in a way and time that suited them.
- The registered manager understood how and when to assess whether a woman had the capacity to make decisions about their care.

Following this inspection, we told the provider that it must take some actions to comply with the regulations and that it should make other improvements, even though a regulation had not been breached, to help the service improve. We also issued the provider with three requirement notices that affected Bayface4d diagnostic imaging. Details are at the end of the report.

Amanda Stamford

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	**Requires improvement** 	We rated the service as requires improvement overall and for safe, and inadequate for well led because there were insufficient processes in place to ensure that the quality and safety of the service was always maintained. We rated the service as good for caring and responsive because feedback from patients was overwhelmingly positive, we observed good care during our inspection, and women could generally access the service when they needed to.

Summary of findings

Contents

Requires improvement

Babyface4d

Services we looked at:
Diagnostic imaging.

Summary of this inspection

Background to Babyface4d

Babyface4d is a private diagnostic service based in Bromsgrove, Worcestershire, and is operated by Pregnancy Ultrasound ltd. The service opened in April 2016 and provides pregnancy ultrasound services to self-funding women, aged 18 years and above. All ultrasound scans performed at Babyface4d are in addition to those provided through the NHS.

The service is registered with the CQC to undertake the regulated activity of diagnostic and screening procedures to women aged 18 years and above. It has had a registered manager in post since registering with the CQC in April 2016.

We have not previously inspected or rated this service.

Our inspection team

The team that inspected the service comprised of a CQC lead inspector and a specialist advisor with expertise in radiography.The inspection team was overseen by Bernadette Hanney, Head of Hospital Inspection.

Information about Babyface4d

Babyface4d is located on the ground floor of a multi-use building which includes a health centre with two separate GP practices, a pharmacy and offices. Facilities include one scan room, and a seated waiting area. The service is registered to provide the following regulated activities:

- Diagnostic and screening procedures.

The service offers diagnostic pregnancy ultrasound scans, including:

- Early pregnancy scans performed from six weeks' gestation.
- Fetal sexing scans performed from 16 to 24 weeks' gestation.
- 4D scan packages performed from 25 to 32 weeks' gestation
- Growth scans and fetal wellbeing performed from 17 to 38 weeks' gestation.
- Presentation scans performed from 37 to 40 weeks' gestation.

All women accessing the services self-refer to the clinic and are all seen as private (paying) patients.

The provider runs two clinics a week from the Bromsgrove clinic which are by appointment only, and standard opening times are Tuesday afternoons from 4pm to 7pm and Saturdays from 8.20am to 3pm. The satellite clinic runs on a Tuesday morning from 8.20 am to 1pm in Chelmsley Wood, Birmingham. The provider told us it sees an average of six women per clinic

At the time of our inspection, Babyface4d employed two members of staff, both on a part time basis; the owner, who was also the ultrasound practitioner, and a receptionist. The ultrasound practitioner was the registered manager.

During our inspection, we visited the registered location in Bromsgrove and we spoke with both staff who worked there. We also observed two ultrasound scan procedures, spoke with two women and their partners, and reviewed three patient records and patient 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.

Activity:

- Babyface4d did not keep detailed records of the number of scans it performed. However, it estimated it had performed a total of 1000 ultrasound scans from February 2018 to January 2019.
- All women were self-funded.

Summary of this inspection

- For the reporting period from November 2017 to October 2018, the service cancelled one clinic which affected six appointments, for non-clinical reasons. The service did not record the number of procedures which were delayed due to non-clinical reasons.

Track record on safety (October 2017 to October 2018):

- The service reported zero never events from November 2017 to October 2018.
- The service had recorded zero incidents from November 2017 to October 2018
- The service reported zero serious injuries from November 2017 to October 2018
- The service received one complaint from November 2017 to October 2018

The service was carried out in a rented clinic room. Facilities included in the rental agreement included:

- Clinical and non-clinical waste removal.
- Daily and weekly clinic cleaning.
- Supply of soap, paper towels and hand gel.
- All maintenance of the clinic.
- There was a service level agreement in place for the ultrasound machine maintenance and repair.

Detailed findings from this inspection

Overview of ratings

Our ratings for this location are:

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

Notes

We do not rate effective.

Requires improvement

Diagnostic imaging

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

Are diagnostic imaging services safe?

Requires improvement

We have not previously inspected this service. At this inspection, we rated safe as **requires improvement.**

Mandatory training

- **While the registered manager 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 service who they regularly worked for. As of February 2019, they had completed the following training: fire safety; infection prevention and control; information governance; conflict resolution; counter fraud; manual handling; prevent training; hospital life support; safeguarding adults level 2 training, which included Mental Capacity Act and Depravation of Liberty Safeguards; and child protection, level 3. Risk, health and safety training had expired and was due for renewal in January 2018 and prior to our inspection, fire safety training had expired in July 2018. Fire training was updated following our inspection.
- The part time receptionist had not completed any work-related training. This included training in fire safety, information governance and equality and diversity, therefore we were not assured the registered manager 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.
- We raised this as a concern during our inspection. The registered manager told us they would ensure their receptionist had an understanding in equality and diversity, safeguarding adults and children and incident and accident reporting, and that this would be completed by May 2019. The provider did not provide evidence that recognised training in these topics would be provided and we were therefore not assured that all staff working in the service had the necessary skills required of their role.

Safeguarding

- **While the registered manager understood the need to protect people from abuse, and had completed safeguarding adults and children training, the receptionist had not received any training in safeguarding adults or children.**
- The registered manager had a good understanding of their responsibilities with regards to recognising and reporting potential abuse. They could describe the steps they would take if they were concerned about the potential abuse.
- The registered manager had up-to-date training in safeguarding adults level two, and child protection level three. However, the part-time receptionist had not completed any training in safeguarding adults or children. This was not in line with national guidance, which states that staff who have contact with adults and children should have both adult and children safeguarding training and this should be updated every three years (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). While the receptionist was never on-site without the registered manager being present, they were alone while they took calls and booked appointments for women.

Requires improvement

Diagnostic imaging

- The provider had a safeguarding policy document which contained details of the local authority safeguarding teams. The policy was not dated, did not have a review by date and it did not contain details of staff training requirements. The policy did not provide staff with any guidance on how to identify or report female genital mutilation (FGM) or child sexual exploitation (CSE). However, the provider had an awareness of FGM and CSE and knew how to report it.
- The provider did not provide pregnancy ultrasound scans to women under the age of 18 years. However, children could attend ultrasound scan appointments with their mothers. The terms and conditions did not state that scanning was provided to women aged 18 years or over, only, and nor did the services website. We were told that women were not asked their age or date of birth upon booking the scan although their date of birth was recorded during the scanning procedure. There had been no instances reported of women under 18 years of age requesting a scan.
- There had been no safeguarding concerns reported to CQC in the reporting period from February 2018 to January 2019.
- The registered manager had undergone a safety check and had a certificate to evidence the checks made by the Disclosure and Barring Service (DBS), at the level appropriate to their role. The receptionist had not undergone a DBS check and the provider told us they believed this was not required due to the size of their service. Non- clinical staff can be exempt from DBS checks in some circumstances where the provider has a clear rationale for not requesting a DBS check, and where a risk assessment for this has been carried out. At the time of our inspection, the provider did not have a risk assessment and we were not assured that all aspects of safety had been considered by the provider. Following our inspection, we were provided with a rationale for not carrying out a DBS check for the receptionist, however they told us they would now apply for this.

Cleanliness, infection control and hygiene

- **While the provider generally controlled infection risks, and the equipment and premises were visibly clean, staff did not always clean their hands in line with best practice.**
- Hand hygiene was not undertaken in line with guidance from the World Health Organisation's 'Five Moments for Hand Hygiene', which states staff should clean their hands before and after every patient contact. We observed two patient ultrasound scans. Staff did not clean their hands before or after either patient. Staff were not bare below the elbows, having long sleeves, a wrist watch and jewellery, although this was addressed following our intervention.
- The provider did not carry out any hand hygiene audits and was unable to evidence that hand cleaning was part of their normal practice.
- There were suitable handwashing facilities for the size and scope of the service. A hand sanitising gel dispenser was available in the scanning room alongside a hand wash basin and paper towels. Hand washing facilities were also available in the toilet.
- Personal protective equipment such as gloves and aprons was available in the clinic. However, we saw that used gloves were disposed of in the household waste bin, despite a clinical waste bin being available in the room.
- The clinic room was visibly clean and tidy. Cleaning was carried out daily in the morning as part of the rental agreement. There was a cleaning schedule in place and this had been signed every day. However, the registered manager did not clean the patient couch themselves prior to using it, nor was it cleaned between each patient use. Tissue paper was used to cover the couch during scanning procedures and we saw this was changed between each patient.
- The clinic room used by Babyface4d was designated as a 'minor operations room', and was also used by other services, including for example, a hair transplant clinic. The registered manager did not carry out any routine cleaning themselves and they had not undertaken any cleaning audits. We were not assured there were processes in place to ensure the premises and equipment were always cleaned as required. Following our inspection, the registered manager implemented a check sheet to be used prior to each session to visually check that the clinic was clean, however the check sheet did not include an instruction to clean the couch before the session started.
- 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

registered manager decontaminated the ultrasound transducer with disinfectant wipes between each client and at the end of each day. The transducer was the only part of the ultrasound equipment that was in contact with women.

- Single use disposable sheaths were used for transvaginal transducers. Transvaginal transducers were also cleaned with disposable wipes. Latex free sheaths were available if women were allergic to latex.
- Staff were unable to tell us how they would clean up spills from bodily fluids, for example vomit or blood, and they did not know how to locate a spills kit on the premises. Following our inspection, the registered manager made an agreement with the health centre that they could use the health centre spills kit if required, until they purchased their own.
- There were no substances hazardous to health used in the service as all cleaning was provided under the rental agreement.
- The registered manager's immunisation history for the prevention of transmissible diseases was not available at the time of our inspection. We requested this data following the inspection and it was provided.
- While the provider had an infection control policy, we found it contained a minimum of information and did not include, for example how to clean up spills of bodily fluids, personal protective equipment requirements, cleaning and use of transvaginal transducers, disposal of clinical waste or any reference to cleaning and hand hygiene audits. Following our inspection, the provider provided an updated standard operating procedure for infection control measures during the clinic sessions. However, we saw that this document remained brief and did not address all the concerns we had raised during the inspection. For example, there was still no requirement that staff be bare below the elbows, or that checks on compliance to hand hygiene would be carried out.
- Flooring throughout the clinic was well maintained and visibly clean. Flooring in the procedure room was in line with national requirements ('Health Building Note 00-10 Part A: Flooring', Department of Health, 2013). The reception area was carpeted, however as no clinical procedures were carried out in this area, there was very little risk of infection from blood or other bodily fluid spillages.
- From November 2017 to October 2018, there had been no instances of healthcare acquired infections (Source: Routine Provider Information Request).

Environment and equipment

- **The provider had suitable premises and equipment and looked after them well.**
- The service was located on the ground floor and was accessible to all women and visitors. The clinic room contained an adjustable couch which staff used to support women with limited mobility.
- The waiting area contained three chairs. However, further seating was available in the main health centre waiting area. There was a disabled access toilet situated close to the clinic and baby changing facilities were available on site.
- The environment in which the scans were performed was spacious, well-lit and well arranged for the purpose of its use. Staff turned the lights off when undertaking a scan to darken the room, which meant scans could be observed clearly.
- The scan room door was lockable, although it was not locked during procedures. We were told it would be locked for transvaginal scans.
- The clinic room had adequate seating for those who accompanied women to their appointment.
- A mobile trolley was used to mount a television, which was used as a slave monitor, and projected the images from the ultrasound machine. This enabled the women and their families to view the baby scan more easily. There was a risk assessment for the cable which ran along the floor from the ultrasound scan machine to the television. However, there was no risk assessment regarding the use of the mobile trolley for the television stand, and there was a risk this could get knocked off and fall off the high trolley.
- An external company completed the servicing of the ultrasound machine. Staff confirmed it had been serviced annually. The machine contained a sticker indicating it had been serviced in January 2019. Where faults arose outside of the planned services, staff called out engineers to assess and perform repairs.
- Electrical equipment was regularly serviced and safety tested to ensure it was safe for patient use. We reviewed three pieces of equipment, including a printer, and the ultrasound machine and found all equipment had been serviced within the date indicated.

- Fire extinguishers were supplied by the building centre and were located in the main reception area, accessible to all clinics. These were stored appropriately and had all been serviced within the date indicated. Routine fire drills had not been held during Babyface4d session times but staff confirmed they knew where the emergency exit points of the building were.
- Waste was not always handled and disposed of in a way that kept people safe. Staff used the domestic waste bin to dispose of gloves which had been used during procedures, despite a clinical waste bin being available in the room. We were not assured that staff were sufficiently aware of guidelines regarding the safe disposal of clinical and non-clinical waste. All bins were emptied by the building facilities team which was included in the rental agreement.
- A first aid kit was available at the centre reception desk. All items in the kit were in date. The health centre had resuscitation equipment including a defibrillator.

Assessing and responding to patient risk

- **While arrangements were in place to assess and manage some risks to women, their babies and their families, not all risks had been identified or mitigated.**
- The provider provided pregnancy ultrasound scans for diagnostic and for keepsake purposes. The terms and conditions for the service indicated that the scan was not a substitute for scans provided by the NHS. We were told women were made aware of this prior to attending 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. However, we saw that the patient information leaflet did not make any reference to the scans being additional to NHS requirements. Additionally, we observed two ultrasound scans and saw neither women were verbally reminded to also attend their routine NHS appointment.
- The registered manager told us they had clear processes in place to escalate unexpected or significant findings identified during ultrasound scans. We saw a patient record where a concern had been referred to an NHS provider. There was a written policy in place for referring women to the NHS when a concern had been identified during the scanning procedure. However, this policy did not include providing the woman with a copy of the scan findings. From December 2018 to 14 February 2019, the provider had made four referrals. During our inspection we were told that there were no documented protocols for how to carry out the different types of scans, for example the protocol for undertaking an early pregnancy scan. Following our inspection, we were provided with written protocols for this and other types of scan.
- The registered manager told us they advised woman to seek immediate advice from their GP, midwife or early pregnancy unit if they had spotting (light bleeding) or were in pain, and were unable to make an appointment at Babyface4d in an appropriate timeframe.
- Women were advised to bring their NHS pregnancy records to their appointment. This meant the registered manager 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 a concern was identified during scanning.
- The provider did not have a policy for identifying and escalating concerns about women who may become ill while using the service, for example if they collapsed. The provider told us they would telephone 999 for urgent support in the event of an emergency. There was also a buzzer in the room which we were told doctors from the centre responded to in the event of the buzzer being activated. However, there was no policy available which confirmed this.
- The registered manager had completed hospital life support (HLS) training as part of their role in the NHS and told us they would put their training to use until a GP from one of the clinics or an ambulance arrived. HLS training gives staff an overview of how to deal with a patient who may have stopped breathing, such as starting cardiopulmonary resuscitation. The receptionist had not received first aid or life support training.
- Staff knew where the nearest automated external defibrillator (used to help resuscitate a patient in cardiac arrest) was located, which was easily accessible at the health centre reception.
- To improve the safety for patients undergoing ultrasound scans, the British Medical Ultrasound Society (BMUS) and Society of Radiographers produced a checklist called 'Paused and Checked', to be used as guidance for sonographers during every patient procedure. While the registered manager did not record the use of the 'Paused and Checked' checklist, the sonographer told us they always completed the checks during their appointments. This included: confirming the woman's identity and consent; providing clear

information and instructions, including the potential limitations of the ultrasound scan; following the BMUS safety guidelines; and informing the woman about the results. The checks were completed but not recorded during the scans we observed.
- Babyface4d website had a frequently asked questions section which contained information about the safety of ultrasound scans and had a link to the BMUS website where more information could be found.
- The provider accepted women who were physically well and could transfer themselves to the couch with little support. However, there were no checks carried out during the booking process to confirm this, and we saw there was no exclusion criteria indicating the circumstances when a scan at Babyface4d would not be appropriate.
- Scan reports were completed immediately after the scan had taken place, which we observed during our inspection.
- Latex-free gloves were used and latex-free covers for the transvaginal ultrasound probe were available for women who had an allergy to latex.

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 registered manager performed pregnancy ultrasound scans at the service. They were supported by a part-time receptionist. The registered manager was always on site when women and their families attended for ultrasound scans.
- There were no staff vacancies at the time of our inspection. The provider did not use any bank, agency or locum staff.

Records

- **While staff kept detailed records of the care they provided, women were not given a written record of the sonographer's findings if there was a fetal concern and if they needed referral to NHS services. Following our inspection, protocols were updated to include the provision of written reports to women who had been referred.**
- At the time of our inspection, the provider told us they did 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 findings. 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 findings to the relevant staff. Following our inspection, the provider updated their procedure for referring women, and this included providing women with a copy of their ultrasound report.
- The only paper records used and stored by the provider were 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. We reviewed two consent forms and found they were complete.
- The terms and conditions document was also classified as the consent form. These were stored securely in a locked cupboard, and destroyed after one month. This prevented unauthorised people from accessing them.
- Scan reports were recorded and stored electronically. The scan forms included the women's identification, the gestation period (the number of weeks of their pregnancy) and the ultrasound images as well as the findings and recommendations. We looked at three scan reports and found they had been fully completed.
- Scans were stored on the ultrasound machine for six months and then removed and archived on an external hard-drive. All electronic devises were protected with a password.

Medicines

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

Incidents

- **While the registered manager understood their responsibility to report, investigate and learn from incidents, there was no system in place to facilitate them in doing this.**
- 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 they had to cancel a clinic due to adverse weather conditions. The

registered manager told us they contacted those women who were booked to attend, apologised, and rearranged their appointments. The registered manager told us there had been no other incidents in the service.

- From November 2017 to October 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 registered manager 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 registered manager was aware of their responsibility to report notifiable incidents to the Care Quality Commission (CQC) and other external organisations.

Are diagnostic imaging services effective?

We do not rate effective.

Evidence-based care and treatment

- **Although the care and treatment provided was based on national guidance and good practice standards, there were limited policies in place, no audits were carried out by the provider and no peer reviews had been undertaken.**
- The sonographer **f**ollowed 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 registered manager completed all ultrasound scans within 15 minutes to help reduce ultrasound patient dose.
- During the ultrasound scan the sonographer followed the principles contained within 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). These checks were not documented; therefore, we were not reassured they were always carried out.
- During the ultrasound scan, the sonographer monitored the thermal index and mechanical index to ensure they both remained within the recommended range for obstetric ultrasound. The sonographers also did not use colour doppler imaging during early pregnancy scans. This was in line with the BMUS and SCoR guidelines.
- There was a protocol for referring women to other services if unexpected or significant findings were found during ultrasound scans and we were shown an example of this during the inspection. The protocol did not include giving women a copy of the scan findings. This was updated following our inspection and included a copy of scan findings for women.
- At the time of our inspection, there were no documented protocols or procedures to follow when conducting various scan types, for example, protocol for conducting a gender scan, or protocol for an early pregnancy scan. Following our inspection, the registered manager wrote relevant protocols for each type of scan.
- There was an appointments protocol in place for staff involved in booking women's appointments. This included ensuring only the sonographer answered any clinical questions women had prior to their scan. The protocol did not include an instruction to remind all women that the ultrasound scans performed at the service were not a replacement for those offered as part of their NHS pregnancy pathway, and it did not specify scans were provided to women aged over 18years only. However, we were told that women were always informed of the need to attend their NHS appointments at the time of booking.

Requires improvement

Diagnostic imaging

- At the time of our inspection, the provider had four policies in place including, infection control, complaints, information governance and safeguarding adults and children. Following our inspection, further policies were produced including incident and accident reporting, quality management policy and a mental capacity policy.
- Some local policies were not in line with current legislation and national evidence-based guidance from professional organisations, such as the National Institute for Health and Care Excellence (NICE). For example, the infection prevention control (IPC) policy did not contain full guidance on hand hygiene, including the need for staff to be bare below the elbows, or to follow the five moments of hand hygiene as recommended by the World Health Organisation. Following our inspection, an IPC standard operating procedure was produced, however this still did not require the sonographer to be bare below the elbows.
- Policies did not contain links to further reading and helpful patient information. For example, links were not available to the leaflets on the Public Health England's website, which includes helpful information regarding the NHS fetal anomaly screening programme.
- Policies did not contain a created or next renewal date. This meant we could not be assured that they were reviewed in a timely manner. Following our inspection, we were told the policies would be dated. However, the policies we were provided with only contained a date of implementation, and not a review by date.
- The terms and conditions included a sentence highlighting the need for women to understand that the services performed at Babyface4d were in addition to those provided as part of their NHS pregnancy pathway and were not designed to replace NHS care.
- The service was inclusive to all pregnant women aged over 18 years old, 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.

Nutrition and hydration

- Women were told they could eat and drink as normal before their scan. 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.

Pain relief

- The registered manager asked women if they were uncomfortable during their ultrasound scans, however, no formal pain level monitoring was undertaken as the procedures were pain free.

Patient outcomes

- **While staff monitored patient outcomes through their activity and patient feedback, peer review audits were not completed in line with national guidance.**
- At the time of our inspection, peer review audits were not undertaken in line with guidance issued by the British Medical Ultrasound Society (BMUS). This guidance recommends that peer review audits are completed using the ultrasound image and the written report. We raised this as a concern during our inspection. We were told that the sonographer had received peer reviews from their substantive employment in the NHS, and that no concerns had been raised about the quality of their reports. Following our inspection, we saw evidence of the quality of the sonographers NHS work, and that regular peer reviews were undertaken on the scan images they produced. However, there was no evidence that peer review audits took place for this service or that these would be undertaken in the future.
- The provider did not monitor its referral to NHS rates and was unable to provide us with accurate numbers of women it had referred during the previous 12 months. However, it told us from December 2018 to 14 February 2019, four referrals had been made.
- The registered manager told us they reviewed the quality of their scan images for baby keepsakes. If they were not happy with the quality, they would contact the woman and invite her for a free scan.
- Women were offered a free scan if the sonographer told them the incorrect gender of their baby. The registered manager told us no women had reported that the gender was wrong in the last 12 months.

Competent staff

Requires improvement

Diagnostic imaging

- **While the sonographer staff file did not contain evidence of appraisals or references, there were processes in place to assess sonographer competence and suitability for their role at another provider. The receptionist did not have a staff folder. Following our inspection, the provider reviewed and updated their personnel folders.**
- Information contained within the sonographers file was limited, and there was no evidence of their recent training, appraisal, employment history or references. The receptionist did not have a staff file or a disclosure and barring service (DBS) check. Following our inspection, a staff file was created for the receptionist, and we saw evidence of the sonographer's appraisal and training records. We were told a risk assessment had been carried out on the requirement for the receptionist to have a DBS check, however we were not provided with a copy of this. Following our inspection, we saw evidence of the rationale as to why the receptionist did not have a DBS check, and we were told that a DBS would now be requested for the receptionist.
- The registered manager had not received an annual appraisal in their substantive role in the NHS. We saw that their last appraisal had been in June 2017.
- We observed the sonographer's practice and found them to be sufficiently skilled, competent and experienced to perform the pregnancy ultrasound scans they provided. They also performed similar ultrasound scans for women at an NHS hospital.
- The sonographer had completed training on using ultrasound equipment. However, they had not been provided with any specific training for the machine they used at Babyface4d. We were told that the scanning equipment was very similar to that used previously, and that they felt specific training was not required.
- The registered manager belonged to the Society of Radiographers, was a trained midwife and was on the Nursing and Midwifery Council (NMC) register. To maintain, NMC registration, midwives must provide a portfolio of evidence to demonstrate their competence. The registered manager's registration was due for renewal in February 2020.
- The registered manager participated in continuing professional development. This was a requirement to remain on the NMC register. We also saw in February 2019, they had contributed to a conference on fetal cardiology.
- The sonographer told us they had not received training on how to use the rented ultrasound machine. However, they told us that the machine was very similar to other machines they had received training on and that they could contact the rental company for advice if required.
- The receptionist had not completed any training relevant to their role and had not received an appraisal. Following our inspection, we were told that this would be reviewed and that in future the receptionist would 'have an understanding' of safeguarding adults and children; incident and accident reporting; and equality and diversity. We were not reassured that all staff would have the relevant skills and knowledge required in accordance with national guidance.

Multidisciplinary working

- The registered manager and the part time receptionist were the only employees in the service. However, they referred women to NHS healthcare professionals to benefit women whenever indicated, and told us they would work together with the local authority safeguarding teams if the need arose.

Seven-day services

- The service provided by Babyface4d was in addition to the 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 providers website contained information on staying healthy during pregnancy. This included advice on diet and exercise, smoking and alcohol, and rest and sleep.

Consent and Mental Capacity Act

- **While staff were aware of the importance for gaining consent from women before undertaking ultrasound scans, informed consent was not always appropriately obtained and documented in line with best practice.**
  - There was no consent policy or a Mental Capacity Act (2005) policy in place at the time of our inspection. Following our inspection, the provider told us they had a mental capacity policy.

- The registered manager told us that implied consent was assumed when women booked their appointment, paid the fee, signed the terms and conditions form, and entered the clinic room. However, women's verbal consent was also sought prior to the sonographer commencing the ultrasound scan.

- Although the sonographer was aware of the need to gain consent before performing ultrasound scans, the practices used by the provider meant they did not always achieve this. The terms and conditions form, which was also used to record consent, was not available in languages other than English and the provider did not use a translation service. Women's relatives or friends were sometimes used as interpreters when English was not the woman's first language. We were concerned that these women may not fully understand what the scan involved or their scan results, and as a result, informed consent could not be appropriately obtained. Following our inspection, the provider told us it would consider using a translation service in future.
- The consent form did not identify what type of scan the women had agreed to, for example whether it was a 4D image scan, or a fetal wellbeing scan. We were therefore not assured that all women using the service were fully aware of what they were consenting to.
- Women who required transvaginal scans did not have their verbal consent recorded. This was not in line with BMUS Guidelines for Professional Ultrasound Practice, 2018, which stated that valid verbal, informed consent for intimate ultrasound examinations should be recorded in the ultrasound report. We were told women who required this type of scan were provided with information about the procedure, and that verbal consent was always obtained. Following our inspection, the registered manager told us that verbally agreed consent would be recorded on the scan record.
- Scans were provided in addition to regular NHS scans, however women were not asked to confirm that they were registered with NHS antenatal services during their clinic appointment. Potential risks to the unborn child from this additional use of ultrasound were not discussed with women and were not highlighted on the consent form. We were not assured that all women had enough information to make an informed decision on whether to proceed with the scan. The service's website contained a link guidance from BMUS.
- Staff obtained women's verbal consent to share information and scan results with their GP, midwife, or other healthcare professional. In these situations, the sonographer explained why this was necessary to the women.
- The registered manager had up to date training in the Mental Capacity Act (2005) and Deprivation of Liberty Safeguards. They reported that they had not seen a woman who lacked capacity since the service opened in 2016.

Are diagnostic imaging services caring?

Good

We have not previously inspected this service. At this inspection, we rated caring as **good.**

Compassionate care

- **Staff cared for women with compassion. Feedback from women and their families confirmed that staff treated them well and with kindness.**
- We spoke with two 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 found the provider 'very reassuring, caring and professional' and another told us they had used the service before because it was 'excellent'.
- The registered manager told us they asked women to leave feedback about their care and a rating of their experience on the service's social media page. Feedback we observed on this page was positive.
- Women's privacy and dignity was maintained during their ultrasound scan, and women were kept covered as far as possible at all times. Women we spoke with confirmed this. However, the room used to carry out all ultrasound scans did not have a privacy curtain or a 'do not enter' sign on the clinic door. There was a risk staff or other women and/or their families could enter the room during a woman's scan. Following our inspection, the provider implemented signs to indicate when the clinic was in use.

Requires improvement

Diagnostic imaging

- During the scans we observed, women were treated sensitively and the sonographer was professional, respectful, and supportive at all times.
- The provider did not offer a chaperone to women. This was not in line with best practice as recommended by the British Medical Ultrasound Society, 2018. Following our inspection, the provider told us it would look further into a chaperone policy.

Emotional support

- **The registered manager provided emotional support to women to minimise their distress.**
- The registered manager was aware that women attending the service were often feeling nervous and anxious, and they provided additional reassurance and support to these women.
- The registered manager told us they frequently referred women to other services because they had identified a fetal concern. They told us how they would communicate this sensitively and would arrange appropriate follow up care. A private room was available for women and those accompanying them to sit in if needed.
- Women who had fetal concerns identified during their scans were offered ultrasound images of their baby. We were told that sometimes women declined these at the time of their appointment. However, the provider kept the images and made them available later in case the women changed their mind. Additionally, images could be printed and provided in a sealed envelope for the women to view in their own time if they chose to do so.
- Due to the nature of the services offered at the clinic, there was usually no further involvement with ongoing care of the women who attended for scans. In the case of miscarriage, there were no patient information leaflets available from the miscarriage association. However, the sonographer encouraged women to contact their midwife or hospital for further support, if required.

Understanding and involvement of patients and those close to them

- **The registered manager involved women and those close to them in decisions about their care and treatment.**
- The registered manager 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 that they 'felt safe asking lots of questions' and that they never felt rushed through the procedure.
- 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 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.
- Women attending for keepsake baby photographs were given the opportunity to reattend for free where a good image could not be obtained on the day. Women whose babies were in a poor position for good scanning images were also offered the opportunity to rescan during their appointment and were encouraged to try and get their baby moving by drinking cold water and mobilising around the reception area.

Are diagnostic imaging services responsive?

Good

We have not previously inspected this service. At this inspection, we rated responsive as **good.**

Service delivery to meet the needs of local people

- **The provider planned its services in a way that met the needs of local people.**
- The facilities and premises were appropriate for the services delivered. The clinic was located on the ground floor of the building, and was accessible to all women and visitors. The scanning room comfortably accommodated four guests and more chairs could be provided if required.
- There was no dedicated reception area for Babyface4d. However, the receptionist could access the health centre desk, if required. The waiting area for Bayface4d was small and consisted of three chairs in a corridor. However, further seating was available in the health centre main waiting area.

Requires improvement

Diagnostic imaging

- While there were no pregnancy related magazines or toys available in the waiting area, most appointments ran on time, and we were told that women were rarely delayed.
- Water was available for women and visitors to help themselves to. There was also a disabled toilet with baby changing facilities. If women wanted to breastfeed in private, staff facilitated this.
- On site car parking was available and was pay and display. The clinic was close to the town centre of Bromsgrove and accessible by public transport.
- Ultrasound scans were available on Tuesday afternoons from 4pm to 7pm and Saturday mornings from 8.20am to 12.30pm.
- Ultrasound scan prices were outlined on the service's website, and we were told that staff clearly explained the costs and payment options to women when they phoned the clinic to make an appointment.
- The provider offered women a range of baby keepsake and souvenir options, which could be purchased for an extra fee. This included a teddy bear with a recording of their baby's heartbeat.

Meeting people's individual needs

- **While the registered manager generally took account of women's individual needs, not all staff had completed equality and diversity training and there was no information available for women who did not have English as a first language.**
- The receptionist had not completed equality and diversity training and there was no equality and diversity policy. Following our inspection, we were told that the receptionist would have an awareness of equality and diversity.
- At the time of our inspection, the provider did not have access to a translation service that could be used during appointments 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 would consider accessing a language service.
- Women were given sufficient time to ask questions before, during and after their ultrasound scan. Women and their partners we spoke with corroborated this.
- Women received a copy of the terms and conditions when they signed and agreed to the procedure. Key information about ultrasound scans was also available on the service's website. However, at the time of our inspection this information was only available in English.
- There was an adjustable couch, which staff also used to support women with limited mobility. However, staff were unaware if there was a weight limit on the couch.
- Although staff were not aware if a woman had a learning disability or mental health condition unless she disclosed it, the registered manager had completed Mental Capacity Act training and would ensure the woman understood what she was consenting to. The registered manager explained all women were treated equally, and care was always adapted to meet their individual care needs.

Access and flow

- **Women could access the service when they needed it.**
- Women could book their appointments online, in person or over the phone. Deposits were not taken and full payment was required on the day of the appointment.
- There was no waiting list or backlog for appointments and last-minute bookings could usually be accommodated. We were provided with an example where a woman booked a same-day appointment.
- Appointments could be booked out of hours when the clinic was not open as all phone calls were transferred to the provider's mobile phone. This helped to reduce anxiety for women who had any concerns and wanted a scan appointment as soon as possible.
- From November 2017 to October 2018, one clinic had been cancelled, and this was due to adverse weather conditions.
- The provider did not keep records of the number of scans it completed, but estimated that from February 2018 to January 2019, it had completed 1000 scans, with an average of 19 scans per week. Non-attendance rates were not monitored.
- The provider did not keep records of the types of scans it completed.

Requires improvement

Diagnostic imaging

- The provider did not keep records of the number of referrals it made. However, from December 2018 to 14 February 2019, four referrals were made to local NHS hospitals.
- Women were not kept waiting when they arrived and had the option to return if they had not been able to get a good photo from the scan due to the position of the baby.
- Women referred themselves for baby keepsake, gender determination and reassurance scans.
- 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

- **The provider treated concerns and complaints seriously, and had a process in place to investigate them, learn lessons from the results, and share these with staff.**
- The provider had a complaints policy in place and this was available on the services website.
- The provider did not use a monitoring system for complaints, such as the date they were received, or the nature of the complaint. However, they had only received one complaint from November 2017 to February 2019. Following the compliant, the provider made it clearer on their website that images obtained during early pregnancy scans could be inconclusive. The provider told us that any concerns raised by women were resolved at the time of their appointment.
- The registered manager told us they investigated complaints and had made changes to information it displayed on its website, as a result of a complaint.
- The sonographer checked that women were satisfied with the service they received before they left the clinic and women were encouraged to provide verbal feedback to staff. However, there were no feedback forms available for women to complete regarding the service. We were told most feedback was received by a social media site. We saw that from January 2018 to February 2019 there had been a total of 25 reviews of the service, which had scored 4.9 out of 5 for customer satisfaction.

Are diagnostic imaging services well-led?

Inadequate

We have not previously inspected this service. At this inspection, we rated well-led as **inadequate.**

Leadership

- **While the registered manager had the skills, knowledge, and experience to conduct ultrasound scans, they had not establishedsuitable and effective policies and procedures to fulfil all of the requirements of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014 (Part 3).**
- The registered manager led the service. They were solely responsible for it and carried out all activities related to it. They were an experienced sonographer and had worked for many years in pregnancy ultrasound scanning departments. Despite this, the provider did not carry out any audits into its effectiveness, and there were no quality assurance measures in place. Peer reviews and quality checks are recommended by ultrasound and radiography professional bodies.
- There was a lack of awareness of the service's performance, limitations, and the challenges it faced. The registered manager was also unaware of the actions needed to address those challenges. For example, the registered manager was unable to suggest how a system of peer reviews could be incorporated into the service, and it did not routinely record the number and type of scans it completed each week/month. Furthermore, the service's website was not up to date at the time of our inspection, and included details of a clinic which it had not opened. Following our inspection, several updates were made to the providers website.
- Due to the small nature of this service, there were no team meetings. However, service activity and patient feedback was discussed between the registered manager and the receptionist regularly to ensure any emerging themes could be identified.
- The receptionist reported directly to the registered manager and told us they had a good working relationship with each other.

Vision and strategy

Requires improvement

Diagnostic imaging

- **The provider had a vision where the delivery of quality care was a priority, and the provider worked to achieve this.**
- The vision for the service was to 'provide customer satisfaction' with high-quality imaging using ultrasound technology in a caring and professional manner.
- The provider was looking at opening a further clinic in another area of Worcestershire in the future to accommodate the extra demand for baby scans.

Culture

- **The provider promoted a positive culture.**
- The registered manager 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 registered manager 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 registered manager 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 at all times.**

- During our inspection, we found the registered manager did not have checks in place to ensure that high standards of care were always maintained. This included relevant and up to date policies and environmental risk assessments, cleaning checks, image report peer reviews, and accident and incident logs. Following our inspection, the provider implemented some immediate changes. This included assessing some of the risks within the service, implementing and updating policies and procedures and accident logs, and carrying out environmental checks and risk assessments. However, although the registered manager had peer reviews of their work in the NHS, there were no plans to establish a peer review process for the quality of the scans completed at Babyface4d, and this was not in line with national guidance.
- Similarly, we were not assured the provider had identified what training in key skills their staff needed. Nor did they have a system in place to ensure they were up to date with their own training. For example, we saw that the registered managers' fire training had been completed in February 2019 following our inspection, however it had been due in July 2018; and risk, health and safety training was out of date, having expired in January 2018 and their last appraisal was in June 2017. The registered manager received specialist sonography training in their substantive role, and this included some skills which were transferable to Babyface4d. Following our inspection, we were told the receptionist would 'have a staff folder to show understanding', in safeguarding adults and children, incident and accident reporting, and equality and diversity, with a completion date by May 2019.
- Protocols for carrying out the various types of scans were not documented. However, following our inspection, these were immediately provided.
- There was a protocol in place for the referral of women with fetal concerns to NHS services. However, this did not include offering woman a written copy of the sonography report, which is regarded as best practice. Following our inspection, protocols were updated to include providing women with a copy of the referral report.
- The sonographer did not have indemnity insurance in place and although this is not a legal requirement, it is recommended by the British Medical Ultrasound Society Guidelines, 2018.
- While risk assessments were available for the premises provided by the health centre managers, there were no specific risk assessments for this service.
- The provider ran a satellite service out of a different clinic. This was not listed on the services Statement of Purpose. Following our inspection, the provider told us they would review guidance on this.

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 registered manager demonstrated some understanding of the potential risks within their service, at the time of our inspection they were unable to evidence risk assessments they had carried out, and

there was no risk register or risk log in place. We were not therefore assured that they had identified risks within their service or that they had acted to minimise those risks. Following our inspection, the provider told us they would review the need for further risk assessments, including a fire risk assessment in the clinic plus a slips trips and falls risk assessment.

- During our inspection we identified a risk relating to the environment not being sufficiently cleaned prior to the service using the room, and a further risk that there was no spills kit available. Following our inspection, the provider implemented a checklist to be completed prior to each session to ensure the room was visually clean, and they had arranged to borrow a health centre spills kit until they purchased their own.

Managing information

- **While the provider used electronic systems with security safeguards, it did not always collect, manage and use information well to support its activities.**
- 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. However, these terms and conditions were not available on the service's website and were given to women to read and sign before the scan was performed at their clinic appointment.
- Scan reports which identified fetal concern information were sent to the woman's NHS provider by email, following an initial telephone call. However, the scan report was only verbally provided to woman, and they did not receive a written report containing this information. Following our inspection, the provider changed its protocol to include providing a written report for women.
- Women's records and scan images were easily accessible and were kept secure. The only paper records were the terms and conditions pages and these were stored in a locked cupboard at the providers home. Electronic systems were password protected.
- The registered manager told us they transferred all scan images onto a CD every six months or sooner if 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 five years at the provider's home. Booking information, including telephone numbers of service users was disposed of after one month, and financial information, such as payment details were disposed of after one week.
- The provider had an information governance policy and the sonographer had completed information governance (IG) training. However, the receptionist had not completed IG training.
- The provider did not keep accurate records of the number and types of scans it completed and when we asked for this information, we were provided with estimates only.
- Information on the services website was not always updated in a timely way. For example, the site advertised a satellite clinic for their service which was ran from West Heath in Birmingham, however we were told on inspection the clinic had not been opened and no appointments were available at this location. This was updated following our inspection. Similarly, we saw that feedback left by women using the service on the website was dated 2015.

Engagement

- **Although the registered manager engaged well with women during their scan procedures, there was limited evidence of engagement outside of the clinic and we found limited evidence of any changes made as a result of comments or complaints received.**
- The provider did not use any customer surveys to gather feedback on the services they provided and nor did they ask women for suggestions on how they could improve. The provider told us women generally reported very positive feedback during their appointment and that if anything had concerned the women, it was resolved at the time.
- The provider asked women to post feedback about the service on their social media web page. We reviewed those made from January 2018 to February 2019 and found 25 women had either left a review or posted a comment.
- We were given an example of an improvement that had been made to the service because of a complaint received. This included making it clearer that early pregnancy scans prior to six weeks gestation, may be inconclusive.
- The provider did not market their services but relied on word of mouth referrals.

Requires improvement

Diagnostic imaging

Learning, continuous improvement and innovation

- **While the provider was committed to learning from when things went wrong, there was limited evidence of promoting training, quality or innovation.**
- The provider did not undertake any continuous improvement or innovation, for example, the registered manager did not have their sonography reports peer reviewed. They did however, undertake continuing professional development activities in their role within an NHS organisation, where their reports were also reviewed.
- The provider took immediate action to understand and address some of the concerns we raised during our inspection. For example, they carried out some risk assessments and provided written protocols for procedures. They also reviewed the training requirements for the receptionist.

Outstanding practice and areas for improvement

Areas for improvement

Action the provider MUST take to improve

- The provider must take prompt action to ensure effective processes for governance and risk management of the service. They must ensure a system is in place to monitor and manage incidents, and risks, and that written policies are in place a process including those to manage incidents, risks, and equality and diversity. Regulation 17 Good governance (1) (2)(a)(b)(d).
- The provider must have a mandatory training programme in place and a system to ensure mandatory training is completed when required, including safeguarding training adults and children for all staff working in the service. Regulation 17 Good governance (1) (2)(a)(b)(d).
- The provider must ensure effective measures are taken to reduce the risk of spread of infection. They must ensure compliance with hand hygiene. Regulation 12 safe care and treatment (1) (2)(h).

Action the provider SHOULD take to improve

- Should consider undertaking peer review audits of the ultrasound scans and reports in accordance with national guidance.
- Should consider providing a chaperone for women who require this, and consider how they could incorporate this into their service.
- Should ensure there are effective governance arrangements in place to assure themselves that staff are competent, of good character and suitable for their role.
- Should consider how they gather feedback from women in order to improve the quality of services provided.
- Should ensure there are translation services available for staff and women to use so that informed consent can always be obtained.
- Should ensure women who are referred for suspected concern to NHS services, are given a written record of the provider's scan findings.
- Should consider taking out legal indemnity insurance.
- Should consider obtaining a DBS check for reception staff.

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 the provider had sufficient governance and risk management systems in place. There was no system in place to monitor and manage incidents and risks. There was system in place to ensure infection control measures were always adhered to. The provider did not have a mandatory training programme in place. Nor were there adequate systems to ensure mandatory training was completed when required.

Regulated activity	Regulation
Diagnostic and screening procedures	Regulation 12 HSCA (RA) Regulations 2014 Safe care and treatment The provider must ensure effective measures are taken to reduce the risk of spread of infection. They must ensure hand hygiene practices comply with national guidelines, including cleaning hands before and after every patient contact and being bare below the elbows while carrying out clinical tasks.