4Dbabyface

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?	Requires improvement

Overall summary

4Dbabyface is operated by Perry & Williamson Limited. Facilities include one consultation room and one reception area.

The service comes under the diagnostic imaging core service but they undertake baby keepsakes as the sole activity which are not diagnostic.

We inspected this service using our comprehensive inspection methodology. We undertook an unannounced inspection on 11 December 2018. 'To get to the heart of women's 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

Summary of findings

We rated it as **Requires improvement** overall.

We found areas of practice that required improvement:

- The service did not have a system to track what mandatory training staff had completed.
- The service did not have someone with level three safeguarding training.
- The service did not have all the required policies in place.
- The service did not have a written process for staff to follow if a woman or visitor deteriorated.
- Staff did not receive documented yearly appraisals.
- The service did not offer Mental Capacity Act training.
- The service did not have any non-English information leaflets or access to a translation service.
- The service had not updated its fire risk assessment.
- The service did not undertake any audits.
- The registered manager did not have information governance training.

We found good practice:

- The service had appropriate staffing levels in place for the amount of women they scanned. The sonographer had the appropriate mandatory training in place.
- The service had suitable premises and equipment and looked after them well. Staff kept themselves, the premises and equipment clean.
- The different kinds of staff within the service worked together as a team to benefit women.
- A Staff at the service treated women with kindness and compassion. Staff provided support for women in times of emotional distress.
- The service planned and provided services in a way that met the needs of women and they could access the service when they wanted to.
- The service engaged well with women, staff, the public to plan and manage its service.
- The registered manager promoted a positive culture that supported and valued staff, creating a sense of common purpose based on shared values. Staff told us the manager was always approachable with any issues.

Summary of findings

Contents

Requires improvement

4Dbabyface

Services we looked at:
Diagnostic imaging

Summary of this inspection

Background to 4Dbabyface

4Dbabyface is operated by Perry & Williamson Limited. The service opened in May 2009. It is a private service which provided souvenir ultrasound scans in Newport, Shropshire. The service primarily served the communities of Shropshire. It also accepted women from outside this area.

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

Our inspection team

The team that inspected the service comprised one CQC lead inspector. The inspection was overseen by Katherine Williams, Inspection Manager.

Information about 4Dbabyface

The service is registered to provide the following regulated activities:

- Diagnostic and screening procedures.

During the inspection, we visited the registered premises, and spoke with three staff including the registered manager, a sonographer and a receptionist. We also spoke with two women and two relatives. During our inspection we reviewed three sets of women records.

All women who used the service were private women. This service provided souvenir ultrasound scans and were not undertaking any form of clinical or diagnostic screening.

The service opened based on bookings from the public, therefore the time of opening varied ever week.

There were no special reviews or investigations of the service on going by the CQC at any time during the 12 months before this inspection. The service was previously inspected in May 2013 under our old methodology, and was found to be meeting all the required standards.

Activity (December 2017 to November 2018)

The service saw 2,608 women. All of these women were privately funded.

Track record on safety

- Zero never events
- Zero clinical incidents

Summary of this inspection

The five questions we ask about services and what we found

We always ask the following five questions of services.

Are services safe?

Requires improvement

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

- The service did not have a system to track what mandatory training staff had completed.
- The service did not have someone with level three safeguarding training.
- The service did not have a safeguarding policy.
- The service did not have an infection prevention control policy.
- The service did not have a policy for staff to follow in the event of a women deteriorating.
- The service did not have a duty of candour policy.

However, we also found the following areas of good practice:

- Staff at the service had training in the key skills they needed.
- Staff understood how to protect patients from abuse.
- The service controlled infection risk well. Staff kept themselves, equipment and the premises clean.
- The service had suitable premises and equipment and looked after them well.
- The service had enough staff with the right qualifications, skills, training and experience to keep people safe from avoidable harm and to provide the right care and treatment.
- Staff kept records of women's personal details. Records were clear, up-to-date and easily available to all staff providing care. Staff had paper and electronic records.
- Staff knew their responsibilities to report any incidents and there was a system in place to deal with incidents.

Are services effective?

- Staff were competent for their roles.
- Staff of different kinds worked together as a team to benefit women.
- Staff gathered consent from the women receiving treatment.

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

- The service did not always provide care and treatment based on national guidance.
- The service did not have an equality and diversity policy.
- Staff did not receive documented yearly appraisals.
  The service did not offer Mental Capacity Act training.

Summary of this inspection

Are services caring?

Good

We rated it as **Good** because:

- Staff cared for women with compassion. Feedback from women confirmed that staff treated them well and with kindness.
- Staff provided emotional support to women to minimise their distress.
- Staff involved women and those close to them in decisions about their care and treatment.

Are services responsive?

Good

We rated it as **Good** because:

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

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

- The service did not have any non-English information leaflets or access to a translation service if needed.

Are services well-led?

Requires improvement

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

- The service did not use a systematic approach to continually improve the quality of its services and safeguarding high standards of care.
- The registered manager in the service did not have all the correct knowledge to run a service providing high-quality sustainable care.
- The registered manager did not ensure that the service had many of the required policies and procedures in place.
- The registered manager did not have information governance training.

However, we also found the following areas of good practice:

- The registered manager promoted a positive culture that supported and valued staff, creating a sense of common purpose based on shared values.
- The service collected and managed information well to support all its activities, using secure systems with security safeguards.
- The service engaged well with women, staff, the public to plan and manage its service

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	Requires improvement	Requires improvement
Overall	Requires improvement	N/A	Good	Good	Requires improvement	Requires improvement

Requires improvement

Diagnostic imaging

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

Are diagnostic imaging services safe?

Requires improvement

We rated it as **requires improvement.**

Mandatory training

- Staff at the service had training in the key skills they needed. However, the service did not have a system to track what mandatory training staff had completed.
- The sonographer had mandatory training in place. The sonographer had in date mandatory training in basic life support, health and safety and safeguarding adults and children level one and two.
- The registered manager did not keep any mandatory training records for staff. The staff could potentially not have the training they needed if they did not have it with another provider. The registered manager might not be aware of this as they kept no training records at the time of inspection.

Safeguarding

- Staff understood how to protect patients from abuse. Not all staff had training on how to recognise and report abuse but there was no formal safeguarding process in place.
- Women were protected from safeguarding abuse as the sonographer and receptionist were aware of their responsibility to protect them. Staff had level one and two safeguarding training for adults and children which they received elsewhere in other roles. Both staff members told us they would contact the registered manager if they thought there was any potential safeguarding abuse.
- The registered manager had a good understanding of their responsibilities with regards to recognising and reporting potential abuse of women from potential safeguarding abuse. The registered manager could describe a situation where they dealt with a potential safeguarding abuse.
- The registered manager was the safeguarding lead for the service. The registered manager did not have level three children's safeguarding training. As the service offered scans to women aged 16 and 17, someone who works within the service should have level three safeguarding and be contactable with any concerns.
- All women were offered the choice of having chaperones during their scans. Women were made aware of this on the legal disclaimer form they signed on arrival. The receptionist would act as the chaperone if it was required.
- The service did not have a safeguarding policy in place. If there was a safeguarding issue it was unclear which process staff would follow.

Cleanliness, infection control and hygiene

- The service controlled infection risk well. Staff kept themselves, equipment and the premises clean. However, a lack of policy meant that they may not be up to date with any changes to infection control processes.

Requires improvement

Diagnostic imaging

- The premises and equipment appeared visibly clean. The staff completed the cleaning themselves. The daily procedure for cleaning was recorded and signed, and the last three months were recorded and kept on site.
- The sonographer cleaned the transducer between different women. The transducer is the only part of the ultrasound machine that makes contact with the women. The sonographer cleaned the transducer using appropriate cleaning wipes.
- Staff and women had access to hand-washing and sanitising facilities. The sonographer used alcohol gel and disposable towels to clean their hands between different women as the handwashing facilities were not in the room used for examinations.
- The sonographer followed 'bare below the elbows' protocol.
- The ultrasound gel used was seen to be in date.
- The service did not have an infection prevention control policy. Due to a lack of policy it would be unclear what standards staff would maintain and whether or not staff could keep up to date with any changes in infection control policy.

Environment and equipment

- The service had suitable premises and equipment and looked after them well.
- The service was on the ground floor of a two-storey building and consisted of a combined imaging and consultation room, a reception and a waiting area. There was an ultrasound machine and associated 'short form' couch. There was a television on the wall which mirrored the ultrasound machine positioned so the women could see it.
- The service had an agreement with another company who would service and repair the machine regularly, in line with the manufacturer's guidelines, when required. The company would also provide a spare machine if the ultrasound machine needed to be taken off site.
- The service also had a senior consultant radiographer who came in regularly to check the radiation levels were within reasonable limits.

Assessing and responding to women risk

- Staff mostly kept women safe from risk and would signpost to outside services if needed. However, as there was no written policy in place, it was unclear what process staff would follow.
- All women scans were for non-clinical purposes and there was no diagnosis involved. As a result, the service did not complete risk assessments for women. Women were made aware of this beforehand and signed a legal disclaimer to say they understood this was the case.
- The sonographer on site was also a trained midwife and formerly a sonographer in the NHS. If any concerns were identified on the scan, the women were referred to the early pregnancy unit or local hospital by the sonographer.
- If the women became really unwell whilst on site staff told us they would call an ambulance.
- The service did not have a written a policy for staff to follow in the event of a women deteriorating. This meant it would be unclear what process staff would follow if a patient or visitor deteriorated.
- The service had a fire risk assessment done in 2012 and had not been updated since. We checked the two fire extinguishers on the premises. We saw that one of the fire extinguishers had all the scheduled checks completed; however, the other fire extinguisher was due to be checked in 2017, which had not been done. The receptionist was made aware of this during the inspection.

Staffing

- The service had enough staff with the right qualifications, skills, training and experience to keep people safe from avoidable harm and to provide the right care and treatment.
- The company employed three sonographers, two reception staff and one manager. However, the same sonographer and receptionist generally ran the clinics.
- There were no vacancies reported at this location.

Records

Requires improvement

Diagnostic imaging

- Staff kept records of women's personal details. Records were clear, up-to-date and easily available to all staff providing care. Staff had paper and electronic records.
- The records did not have any clinical information in them. They had a unique reference number, a foetal checklist, baby position and a box for any additional comments. These were stored with a legal disclaimer signed by the women.
- Women records were managed in a way that kept their confidential and sensitive information from being shared incorrectly. Women records were stored in locked filing cabinets for seven years before they were destroyed.
- The service was registered with the Information Commissioner's Office (ICO).

Medicines

- The service did not use any controlled drugs or medicines.

Incidents

- Staff knew their responsibilities to report any incidents and there was a system in place to deal with incidents.
- The service had an accident book which was used to report accidents if it was needed, however we noted there were none reported between 1 December 2017 and 30 November 2018.
- The service had zero incidents between 1 December 2017 and 30 November 2018.
- Staff told us if there was an incident or complaint they would report it to the registered manager.
- The registered manager was aware of their responsibility to report any incidents. The registered manager was aware of 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 women (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 service did not have a duty of candour policy.

Are diagnostic imaging services effective?

Evidence-based care and treatment

- The service did not always provide care and treatment based on national guidance.
- The service delivered care in line with the
- The service did not have any internal guidance in place based on national guidelines.
- The registered manager told us she was assured that staff would not discriminate on the grounds of age, disability, gender, gender reassignment, pregnancy and maternity status, race, religion or belief and sexual orientation. However; the service did not have an equality and diversity policy.

Patient outcomes

- The service did not measure any women outcomes.

Competent staff

- Staff were competent for their roles.
- Sonographers do not have a protected title and are therefore not required to be registered with the Health and Care Professions Council (HCPC).
- The registered manager checked on the status of sonographers' professional qualification and Disclosure and Barring Service (DBS) every 12 months and sent this information to the insurance company.
- The service is delivered by one sonographer and one receptionist at any one time. None of the scans were diagnostic or clinical. The sonographer who worked at the location was not currently working at another NHS hospitals or going through the process of registering with the society of sonographers' voluntary register.
- The registered manager spoke to staff members regularly about any extra training they might want or need; however, staff did not receive documented yearly appraisals.

Multidisciplinary working

- Staff worked together as a team to benefit women.

Diagnostic imaging

- The sonographer and receptionist had a good working relationship.
- The sonographer would refer women to outside agencies, such as the early pregnancy unit and accident and emergency, if they suspected there was an issue. The sonographer would not diagnose the issue or reveal and details to the women if they suspected there was an issue.

Seven-day services

- The service ran clinics based on availability of staff and bookings from the public. These could be any day of the week and ran for as long as needed.

Consent and Mental Capacity Act

- Staff understood the need to gain consent from the women receiving treatment.
- Staff had some understanding of the Mental Capacity Act 2005. However, staff had no Mental Capacity Act training and the service had no Mental Capacity Act policy in place.
- Women's consent was gained before the ultrasound test. This was done when women signed the legal disclaimer form. Women had the procedure explained to them before the scan had taken place, and all women self-referred to the service. The service was transparent with its pricing and these were displayed on leaflets, on the premises and discussed with potential women on the phone.
- The registered manager understood their responsibilities with regards to capacity to consent. The registered manager gave an example of when there was a concern with regards to capacity to consent. The service did not offer mental capacity act training.
- The service did not have a Mental Capacity Act policy.

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.
- The service actively sought the views of women. Women were encouraged to leave feedback on social media. The average score for the service was 4.4 out of five. Women commented that the service was a "great place", "staff made us so welcome", "they go above and beyond" and "highly recommended".
- The registered manager gave examples of treating women compassionately when they were anxious or when women had received distressing or upsetting news with regards to the baby.
- The environment ensured women's privacy and dignity was maintained. The consultation room was private and therefore, only the women and person(s) with them were present along with the sonographer. The women were provided with paper towels whilst they were being scanned.
- The receptionist assisted women promptly and were friendly and efficient.

Emotional support

- Staff provided emotional support to women to minimise their distress.
- The service actively encouraged staff to make sure women and their families enjoyed their baby scanning experience.
- Staff discussed procedures with women and they were encouraged to be part of the decision-making process.
- The service had a strong, visible person-centred culture. The registered manager was highly motivated. Women were actively involved in their care.
- Staff understood the impact that women's scans had on their wellbeing. Staff treated women as individuals.
- The sonographer talked to women during procedures to put them at ease.

Understanding and involvement of women and those close to them

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

Requires improvement

Diagnostic imaging

- Staff communicated with women so that they understood their care, treatment, and condition.
- Women said that staff were thorough, took time to explain the procedures to them, and they felt comfortable and reassured. Women felt they were given adequate information.
- Women were provided with appropriate information about pricing and scan options before their visit.

Are diagnostic imaging services responsive?

Good

We rated it as **good.**

Service delivery to meet the needs of local people

- The service planned and provided services in a way that met the needs of local people.
- Women's individual needs and preferences were central to the planning and delivery of the service. The service was flexible and provided choice of scan options and appointment times.
- The service offered confirmation of pregnancy scans, 2D gender scans, 4D gender scans, reassurance scans, bonding scans, and weight estimation scans.
- The environment was appropriate and women centred. There was a comfortable seating area and toilet facilities for women and visitors.
- Women were seen promptly. Staff would extend clinic times if there was enough demand from women.
- Women had good access to the centre by car and public transport. The reception area was clean and tidy with access to magazines and, children's toys.

Meeting people's individual needs

- The service mostly took account of women's individual needs.
- The service could not be fully accessed by people with limited mobility as there were three stairs from the reception area into the consultation room. The other two branches of the same service were fully accessible and this was always explained to women when they booked. The service advertises that the other branches are wheelchair accessible and this one is not.
- The service did not have any information for non-English speakers who might access the service. Staff told us that when non-English speakers attended the service they would usually be with a family member who could translate for them. Staff did not use a translation service.
- The service used the examination room as a quiet room if it was required.

Access and flow

- People could access the service when they wanted it.
- Women could book appointments online or by phone. During this time, they would inform the service the type of scan they wanted and preferred appointment time.
- Women were offered a choice of appointment times. The service planned to scan women at the nearest available clinic time to when the women requested. There were usually two clinics a week.
- The service mostly ran on time and staff informed women when there were disruptions to the service. Women were sometimes delayed due to the positioning of the baby causing scans to be more difficult but this was always explained to women.
- The service did not have any urgent referrals.

Learning from complaints and concerns

- The service treated concerns and complaints seriously, investigated them and learned lessons from the results, and shared these with all staff.
- The service had a complaints policy. The complaints policy detailed the services commitment to the customer, told the customer how to complain and outlined the response time.
- Information on how to make a complaint was readily accessible to women. For example, leaflets or a notice in the reception area.

Requires improvement

Diagnostic imaging

- The receptionist would usually handle any informal complaints or concerns from women at the time of the scan and these were mostly dealt with immediately. Patients were offered often offered re-scans when the appropriate scan imagine could not be obtained.
- The registered manager was aware of their responsibilities in handling complaints and would handle any formal complaints.
- The service received zero formal complaints from 1 December 2017 to 30 November 2018.

Are diagnostic imaging services well-led?

Requires improvement

We rated it as **requires improvement.**

Leadership

- The registered manager in the service did not have all the correct knowledge to run a service providing high-quality sustainable care.
- The registered manager did not ensure that the service had all the required policies and procedures in place. For example, safeguarding, infection control, duty of candour, equality and diversity, Mental Capacity Act and deterioration of patients policies.
- The registered manager told us the main challenges to care and treatment, and explained how they dealt with them and the plans they had in place.
- Staff told us that the registered manager was approachable with any problems or issues that they might have. The registered manager was not based in the building but could always be contacted by phone and email.

Vision and strategy

- The service did not have a documented vision and strategy. The registered manager told us the vision and strategy was 'Private foetal ultrasound clinic performing entertainment leisure scans to paying clients. Scans carried out by holistic qualified midwife sonographers or radiographers employed within the NHS in some cases'.

Culture

- The registered manager promoted a positive culture that supported and valued staff, creating a sense of common purpose based on shared values.
- All staff members were focussed on creating a positive experience for the women and getting the best possible images.
- The service had an open and honest culture. Staff were always open with women when they could not get the best possible scan photos for them.

Governance

- The service did not use a systematic approach to continually improve the quality of its services and safeguarding high standards of care.
- The service did not have several of the required policies in place. This meant standard procedures were not documented and practice was not reviewed on a regular basis.
- The service had no system in place to monitor staff members mandatory training. This meant that the registered manager was not aware when a staff members training was no longer in date.
- The service did not undertake any audits. This meant that the service could not be fully assured that its staff members complied with certain standards i.e. handwashing and cleanliness.
- The service checked sonographers' disclosure and barring service (DBS) and right to practice on a yearly basis for insurance purposes. The service paid for the insurance.
- Staff at the service did not have formal sit-down team meetings. Staff could raise any issues or problems with the registered manager at any time and staff told us that the registered manager was responsive and took issues seriously and actioned them as a result.

Managing risks, issues and performance

- The service had undertaken both health and safety and fire risk assessments. However, the fire risk assessment had not been updated since 2012, and we identified that one of the fire extinguishers had not received its scheduled check.
- The service did not undertake and audits or measure any patient outcomes in order to improve practice.

Diagnostic imaging

- The registered manager told us what they would do if they had any issues with staff performance. The registered manager told us they would monitor new staff member performance and check on them more regularly.

Managing information

- The service collected and managed information well to support all its activities, using secure systems with security safeguards.
- All women's records were confidential and women's identities were protected. All women had a unique reference number.
- The service was registered with the Information Commissioners Office (ICO).
- The registered manager was the data controller for the service.
- The registered manager did not have information governance training.

Engagement

- The service engaged well with women, staff, the public to plan and manage its service.
- The registered manager worked closely with a small and well-integrated team. Staff had regular input about the service and any changes that might occur. Staff told us they felt engaged with any decisions that were made about the service.
- The service used feedback from women to improve service provision. For example, the registered manager put children's toys in the reception area following women's feedback.
- The service used social media to gather women's feedback and engaged with women through this medium.

Learning, continuous improvement and innovation

- The service did not undertake any continuous improvement or innovation.

Outstanding practice and areas for improvement

Areas for improvement

Action the provider MUST take to improve

- The registered manager must have a system in place to keep track of what mandatory training the sonographers have completed. This was a breach of Regulation 17 (1) HSCA 2008 (Regulated Activities) Regulations 2014 Safe care and treatment – Good governance.
- The registered manager must ensure someone within the service has children's level three safeguarding training. This was a breach of Regulation 13 (2) HSCA 2008 (Regulated Activities) Regulations 2014 – Safeguarding service users from abuse an improper treatment.
- The registered manager must ensure that all the required policies are written and put in place. This was a breach of Regulation 17 (1) HSCA 2008 (Regulated Activities) Regulations 2014 Safe care and treatment – Good governance.

Action the provider SHOULD take to improve

- The registered manager should ensure the service has a process in place in case of deterioration of women.
- The registered manager should ensure that staff have documented yearly appraisals.
- The registered manager should ensure that relevant staff members have Mental Capacity Act training.
- The registered manager should ensure that leaflets and information is available in other languages and a translation service available if needed.
- The service should ensure it undertakes audits to safeguard high standards of care.
- The service should ensure that it updates the fire risk assessment on a regular basis.
- The registered manager should ensure they have information governance training as the data controller for the service.

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 13 HSCA (RA) Regulations 2014 Safeguarding service users from abuse and improper treatment There was no staff member at the service with level three safeguarding training. Regulation 13 (2)

Regulated activity	Regulation
Diagnostic and screening procedures	Regulation 17 HSCA (RA) Regulations 2014 Good governance The service did not have all the required policies in place. There was no system in place to monitor mandatory training. Regulation 17 (1)