Early Days Baby Scan Ltd

Quality Report

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

Ratings

Overall rating for this location	**Good**
Are services safe?	**Good**
Are services effective?	**Not sufficient evidence to rate**
Are services caring?	**Good**
Are services responsive?	**Good**
Are services well-led?	**Good**

Overall summary

Early Days Baby Scan Ltd is an independent medical provider offering antenatal ultrasound imaging and diagnostic services to self-funding or private patients.

Early Days Baby Scan Ltd is located in Wakefield town centre, and is served by good public transport links. The location benefits from on-street public parking, and private car parks are available close by. The service is located on the ground floor of a business property. The reception and waiting area has sufficient seating, and leads on to a bathroom. Refreshments and entertainment (radio and magazines) are available whilst waiting. Ultrasound scanning takes place in an adjacent private room with ample space and seating.

The service offers early pregnancy reassurance (from six to 15 weeks pregnancy), sexing/gender (from 15 weeks pregnancy), 3D and 4D (from 24 to 32 weeks pregnancy), reassurance (from 15 weeks pregnancy), and presentation (from 35 weeks pregnancy) ultrasound

Summary of findings

scans. Depending on the type of scan performed, these might involve checking the location of the pregnancy, dating of the pregnancy, audio fetal heartbeat check, determination of sex, and fetal presentation at the time of appointment. All ultrasound scans are performed transabdominally. Patients are provided with ultrasound video or scan images, and an accompanying verbal explanation or written report.

We inspected the service using our comprehensive inspection methodology. We carried out a short-announced inspection on 18 January 2019. We had to conduct a short-announced inspection because the service was only open if patient demand required it.

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 fundamental standards.

Services we rate

We had not previously inspected this service. We rated it as **Good** overall.

We found the following areas of good practice:

- There were procedures in place for referral to other agencies; such as NHS antenatal healthcare providers, and local authority safeguarding teams. Staff understood how to protect patients from abuse.
- Staff understood how to keep people safe from avoidable harm and to provide the right care and treatment. The service had systems in place to manage patient safety incidents well.
- The service treated concerns and complaints seriously, and had systems in place to investigate them and learn lessons from the results.
- The service had suitable premises and equipment and looked after them well. The service controlled infection risk and staff kept equipment and the premises clean.
- Staff completed and updated risk assessments and care records for each patient. The service had policies and procedures in place to promote the confidential and secure processing of information held about patients.
- We saw extensive evidence of positive feedback from women who had used the service; including from women who had received challenging news, and those who had previously experienced pregnancy loss.
- We saw the service had voluntarily refunded deposits for women who had cancelled appointments due to pregnancy loss; and had provided complementary repeat sexing/gender scans if the baby's sex could not be determined at the time of appointment.
- Staff understood the importance of obtaining informed consent, and involved patients and those close to them in decisions about their care and treatment.
- The service planned and provided services in a way that met the needs of local people and took account of patients' individual needs.
- Managers in the service and had the right skills and abilities to run a service providing high-quality sustainable care and promoted a positive culture.
- The service was committed to improving services, had a vision for what it wanted to achieve, and engaged well with patients to plan and manage appropriate services.

However, we found the following issues that the service provider needed to improve. These findings were fed back at the time of inspection:

- We observed that consent forms at the service didn't clearly follow Public Health England (PHE) guidance.
- The service did not have a specific consent form for patients under 16 years of age which evidenced use of the Gillick competence test.

Following our inspection, we told the provider that it should make some improvements, even though a regulation had not been breached, to help the service improve. Details are at the end of the report.

Summary of findings

Ellen Armistead Deputy Chief Inspector of Hospitals (Hospitals)

Summary of findings

Our judgements about each of the main services

Service	Rating	Summary of each main service
Diagnostic imaging	Good 	Early Days Baby Scan Ltd is an independent medical provider offering antenatal ultrasound imaging and diagnostic services to self-funding or private patients. The service offers early pregnancy reassurance (from six to 15 weeks pregnancy), sexing/gender (from 15 weeks pregnancy), 3D and 4D (from 24 to 32 weeks pregnancy), reassurance (from 15 weeks pregnancy), and presentation (from 35 weeks pregnancy) scans. Depending on the type of scan performed, these might involve checking the location of the pregnancy, dating of the pregnancy, audio fetal heartbeat check, determination of sex, and fetal presentation at the time of appointment. All ultrasound scans are performed transabdominally. Patients are provided with ultrasound video or scan images, and an accompanying verbal explanation or written report.

Summary of findings

Contents

Good

Early Days Baby Scan Ltd

Services we looked at
Diagnostic imaging

Summary of this inspection

Background to Early Days Baby Scan Ltd

Early Days Baby Scan Ltd is operated by Early Days Baby Scan Ltd. It is a private ultrasound scanning service, which opened in Wakefield town centre in February 2017. The service is managed and operated by two business partners. One partner is the registered manager and provides clinical services (is the scan practitioner), and the other partner is the business manager for the service. The service does not employ any additional staff. The service primarily serves the communities of Wakefield and outlying areas.

The service has had a registered manager in post since it began trading in February 2017. The service is registered for the following regulated activities:

- Diagnostic and screening procedures

We conducted a short-announced inspection of the service on 18 January 2019. We had not previously inspected this service.

Our inspection team

The team that inspected the service comprised a CQC lead inspector and team inspector. The inspection team was overseen by Sarah Dronsfield, Head of Hospital inspection.

Information about Early Days Baby Scan Ltd

The clinic is registered to provide the following regulated activities:

- Diagnostic and screening procedures

The service offers a variety of trans-abdominal ultrasound scans to pregnant women, from six weeks fetal gestation. The service does not have a lower age limit, and occasionally provides services to patients under 16 years of age. Scans can involve diagnostic checks, such as determining the location and dating of the pregnancy, audio fetal heartbeat, sex, and presentation. Patients are provided with ultrasound video, scan images, audio recordings, and an accompanying verbal explanation or written report; depending on the nature and outcome of the scan undertaken. The service does not provide any additional diagnostic services, such as non-invasive pre-natal testing (NIPT) or endometrial thickness measuring (for women undergoing fertility treatment).

During the inspection, we spoke with two staff; the registered manager (who is the ultrasound scan practitioner) and the business manager. We observed six ultrasound scans, and spoke with these six patients and their companions. We reviewed eight patient records. We reviewed staff records, primarily in relation to the scan practitioner (registered manager).

There were no special reviews or investigations of the service ongoing by the CQC at any time during the 12 months before our inspection. We had not previously inspected this service.

Activity – 01 November 2017 to 01 November 2018 (reporting period):

In the reporting period, the service undertook a total of 2453 ultrasound scans. This was comprised of the following:

- 1326 early pregnancy reassurance scans (from six to 15 weeks pregnancy);
- 700 sexing/gender scan (from 15 weeks pregnancy);
- 328 3D and 4D scans (from 24 to 32 weeks pregnancy);

Summary of this inspection

- 92 reassurance scans (from 15 weeks pregnancy); and
- 7 presentation scans (from 35 weeks pregnancy).

In this timeframe, the service did not receive any written complaints, and received 142 written compliments.

Track record on safety during the reporting period:

- There were no patient deaths, never events, or serious incidents. Never events are serious patient safety incidents that should not happen if healthcare providers follow national guidance on how to prevent them. Each never event type has the potential to cause serious patient harm or death but neither need have happened for an incident to be a never event.
- There was no duty of candour notifications. 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.
- No safeguarding referrals were made.
- There was no incidence of healthcare acquired infections.
- There was no unplanned urgent transfer of a patient to another health care provider.
- The service did not cancel any appointments for a non-clinical reason.

Summary of this inspection

The five questions we ask about services and what we found

We always ask the following five questions of services.

Are services safe?

Good

We had not previously inspected this service. We rated safe as **Good** because:

- 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 service had systems in place to manage patient safety incidents well.
- Staff understood how to protect patients from abuse and the service had systems in place to do so.
- The service had suitable premises and equipment and looked after them well. The service controlled infection risk and staff kept equipment and the premises clean.
- Staff completed and updated risk assessments for each patient. Staff kept detailed records of patients' care and treatment. Records were clear, up-to-date and easily available to all staff providing care.

However:

- Consent forms were not in line with Public Health England (PHE) guidance.

Are services effective?

Not sufficient evidence to rate

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

- The service provided care and treatment based on national guidance and evidence of its effectiveness.
- The service made sure staff were competent for their roles.
- There were referral pathways to other agencies in place for staff to follow to benefit patients.
- Staff understood the importance of obtaining informed consent.

However:

- The service did not have a consent and mental capacity act policy for staff to follow. However, we saw evidence that the sonographer had been trained to assess mental capacity.
- The service did not have a specific consent form for patients under 16 years of age which evidenced use of the Gillick competence test.

Summary of this inspection

Are services caring?

Good

We had not previously inspected this service. We rated caring as **Good** because:

- Staff cared for patients with compassion. The service evidenced extensive positive feedback from patients, which confirmed that staff treated them well and with kindness.
- The scan practitioner had counselling and bereavement qualifications, and provided emotional support to patients to minimise their distress. We saw positive feedback about the "incredible" service from women who had received challenging news, and who had experienced pregnancy loss.
- We saw the service had voluntarily refunded deposits for women who had cancelled appointments due to pregnancy loss; and had provided complementary repeat sexing/gender scans if the baby's sex could not be determined at the time of appointment.
- The service positively encouraged participation, and staff closely involved patients and those close to them in decisions about their care and treatment. Staff communicated clearly, demonstrated patience, allowed good time for questions, and appropriately answered these.

Are services responsive?

Good

We had not previously inspected this service. We rated responsive as **Good** because:

- The service planned and provided services in a way that met the needs of local people.
- The service took account of patients' individual needs.
- People could access the service when they needed it. The service opened according to patient demand, and offered a number of appointment booking methods.
- The service treated concerns and complaints seriously, and had systems in place to investigate them and learn lessons from the results, and share these with all staff.

However:

- Staff told us that there was no provision of information in any language other than English.

Are services well-led?

Good

We had not previously inspected this service. We rated well-led as **Good** because:

- Managers in the service had the right skills and abilities to run a service providing high-quality sustainable care, and promoted a positive culture.

Summary of this inspection

- The service had good systems to identify risks, plan to eliminate or reduce them, and cope with both the expected and unexpected.
- The service had policies and procedures in place to promote the confidential and secure processing of information held about patients.
- The service was committed to improving services, had a vision for what it wanted to achieve, and engaged well with patients to plan and manage appropriate services.

Detailed findings from this inspection

Overview of ratings

Our ratings for this location are:

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

Good

Diagnostic imaging

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

Are diagnostic imaging services safe?

Good

We rated the safe domain as **good.**

Mandatory training

- The service provided mandatory training in key skills to all staff.
- We saw evidence the scan practitioner was trained to competently use the ultrasound equipment at the premises. For example, the practitioner had completed 3D obstetrics (level one), and optimisation (level two) training provided by the manufacturer.
- In addition to training provided by the manufacturer, the scan practitioner had completed a range of accredited ultrasound training courses. For example, pregnancy dating training, and second/third trimester ultrasound measurement training (both provided by the British Pregnancy Advisory Service); which included evidencing at least 14 hours of professional practice. They had also completed a centre for ultrasound studies, '2nd Trimester Ultrasound Measurements' course (accredited by the Royal College of Radiographers).
- Staff undertook regular self-directed and formal continuing professional development training; we saw this included training around British Medical Ultrasound Society (BMUS) standards and meeting Nursing and Midwifery Council (NMC) requirements for registered midwife revalidation.

Safeguarding

- Staff understood how to protect patients from abuse and the service had systems in place to do so.
- The service had an up to date protection of vulnerable adults and children safeguarding policy; which detailed possible types of abuse, individual and organisational reporting responsibilities, referral pathways, and contact details for local authority safeguarding teams.
- The scan practitioner was the children and adults safeguarding lead for the service. The practitioner was trained to level 3 safeguarding children (which included elements of multi-agency training as per intercollegiate guidance 2015), and level 2 safeguarding adults.
- The business manager was trained to level 2 safeguarding children, and level 2 safeguarding adults.
- In the twelve months prior to inspection no safeguarding referrals had been made by the service.
- There was no written policy to support staff in reporting female genital mutilation (FGM); nor did we see FGM mentioned in the safeguarding policy. However, as all ultrasound scans were performed transabdominally, this was unlikely to be an issue for staff at the service.
- We saw evidence that all staff had a current Disclosure and Barring Service (DBS) check.

Cleanliness, infection control and hygiene

- The service controlled infection risk well. Staff kept equipment and the premises clean. They used good control measures to prevent the spread of infection.

Good

Diagnostic imaging

- The service had an up to date infection control policy. The scan practitioner at the location was the infection control lead for the service.
- The service had appropriate handwashing facilities (including in the treatment room), and also utilised alcohol gel. Clinical staff were bare below the elbows.
- The couch in the treatment room used by patients was covered with disposable cloth which was changed between patients and the couch wiped with an antibacterial wipe before laying out a new disposable cloth.
- Procedures carried out at the location were non-invasive (external); all ultrasound scans were performed transabdominally and involved minimal contact with patients. We observed the ultrasound probe was cleaned before and after patient use with an antiseptic wipe.
- In the twelve months prior to inspection there had been no incidences of healthcare acquired infections.

Environment and equipment

- The service had suitable premises and equipment and looked after them well.
- The location was served by good public transport links, and there were car parking facilities nearby. We were informed that the layout of the premises was exclusively designed for the service's business use.
- The reception and waiting area had sufficient seating, and bathroom amenities were available. Refreshments and entertainment (radio and magazines) were offered to patients and their companions whilst they waited.
- The treatment room contained a treatment couch and a large television monitor was mounted to the wall, on which sonogram images were displayed. There was an ultrasound system and a laptop computer, which both securely linked to a computer in the main reception area. The room was spacious, with seating for up to five companions and additional standing room. The environment promoted the privacy and dignity of women.
- There was an up to date Health, Safety and Environment Risk Assessment policy in place, and we saw evidence that local risk assessments had been conducted.
- We saw that cleanliness, hygiene, and personal and protective equipment (such as gloves and wipes) were readily available.
- Staff told us that they regularly checked stocks at the location, and we saw there was adequate storage facilities for consumables.
- We saw the ultrasound machine was maintained and serviced in line with the manufacturer's guidance. The equipment had been serviced in the 12 months prior to our inspection, and we saw evidence of an upcoming annual service.
- The service had appointed an external company to undertake a fire risk assessment in the 12 months prior to our inspection; and we saw evidence of compliance.

Assessing and responding to patient risk

- Staff completed and updated risk assessments for each patient. They kept clear records and asked for support when necessary.
- The service had an up to date risk assessment policy and procedure.
- The service had a patient consent form for the different type of scans provided. Staff told us these were used to inform patients about the services provided, and to encourage discussion of requirements and potential concerns prior to any service being carried out.
- We saw that written information provided by the service (on site and on line) strongly advised women to attend scans as part of their NHS maternity pathway. As part of giving their consent, women had to declare that they had already contacted their GP regarding the pregnancy, and were engaged in an appropriate programme of antenatal care.
- Consent forms advised women that scans were conducted according to British Medical Ultrasound Society (BMUS) recommendations for 'as low as reasonably achievable' (ALARA) principles for safety in ultrasound scanning; for length of scan and frequency

of ultrasound waves. The service's website contained a link to Public Health England (PHE) guidance. Current PHE guidance describes that, although there is no clear evidence that 'souvenir scans' are harmful to the fetus, parents-to-be must decide for themselves if they wish to have souvenir scans and balance the benefits against the possibility of unconfirmed risks to the unborn child. However, we saw consent forms at the service described that "… no proven detrimental effects have been found in over 40 years of studies". This was not in line with PHE guidance about the possible risks of frequent ultrasound scanning; and this was fed back to the service at the time of inspection. Following our inspection, the service provided evidence to show that consent forms had been updated in line with PHE guidance.

- We observed that written information and verbal information given to women who utilised the service was clear as to the limits of diagnostic services provided. For example, when giving written consent, women had to declare that they understood that "the scan practitioner is unable to give robust diagnostic opinion nor medical advice in this context … if the scan reveals a possible anomaly … confirmation of the nature and implications of this can only be given to me by my antenatal care provider".
- All scan results were immediately available and reported to patients. With patient consent, if follow-up was required, the service could supply scan results to third party healthcare professionals. This was then followed by a written report which, with patient consent, was copied into their GP or other care provider. During our inspection, we observed examples of referrals made to antenatal care providers. For example, in one case we saw that the scan practitioner had not detected the baby's heartbeat, and had referred the patient to a hospital early pregnancy unit.
- If a patient waiting to be seen suddenly deteriorated staff told us that the procedure was to call an ambulance using 999 and to administer basic life support. We were told that the service did not operate unless both the scan practitioner and business manager were present onsite; and we saw this was reflected in company policy.
- In the 12 months prior to our inspection, the service reported there had been no unplanned urgent transfers of a patient to another health care provider, and no appointments had been cancelled for a non-clinical reason.

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 service staffed the location on an 'as needed' basis in line with patient demand; with a qualified and accredited clinical staff member who provided ultrasound scanning services, and a business manager who managed the reception area and undertook administrative tasks. The service did not employ any additional staff.
- In the period November 2017 to November 2018, there had been no vacancies for directly employed staff and the service did not use bank or agency staff. There had also been no sickness absence in this period.

Records

- Staff kept detailed records of patients' care and treatment. Records were clear, up-to-date and easily available to all staff providing care.
- Consent forms ensured sufficient information was obtained from women prior to their scans; for example, in relation to number of weeks pregnant, and number of previous pregnancies. Women were also made aware of (and agreed to) informing a member of staff if they had received any medical care or experienced symptoms (such as bleeding or abdominal pain) within 72 hours before having the scan; or if they had a medical condition (such as gestational diabetes or uterine fibroids) that might affect their scan.
- We saw the service had an up to date policy for the creation, management, handling and storage of records and information.
- Early Days Baby Scan was registered with the Information Commissioner's Office (ICO) and held a current certificate relating to this registration.

Good

Diagnostic imaging

- Patient records were in electronic format. Access to systems was password protected, and electronic documents were encrypted and securely stored in The Cloud. Paper records were scanned and entered onto the patient electronic record, then securely destroyed.
- With prior consent from the patient, records could be shared with third party healthcare professionals, such as GPs or NHS maternity/gynaecological services.

Incidents

- The service had systems in place to manage patient safety incidents well.
- The service had a notification policy and procedure for external reporting; which included examples of incidents that should be reported to CQC. Staff we spoke with understood the types of incidents they might report, and understood their responsibilities to raise concerns, to record safety incidents, concerns and near misses; and to report them internally and externally, where appropriate.
- Staff said they would be open and honest with patients should anything go wrong, and give patients suitable support.
- In the reporting period November 2017 to November 2018, there were no patient deaths, never events, or serious incidents. In the same period, there was no duty of candour notifications.

Are diagnostic imaging services effective?

Not sufficient evidence to rate

The effective domain was not rated.

Evidence-based care and treatment

- The service provided care and treatment based on national guidance and evidence of its effectiveness.
- We observed that clinical (ultrasound scanning) guidelines used by the service adhered to United Kingdom Association of Sonographers (UKAS) guidelines.
- We saw evidence that the clinical staff member working at the location was familiar with BMUS guidance and recommendations, and had attended national BMUS conferences about ultrasound practice.

Nutrition and hydration

- Patients had access to enough food and drink to meet their needs.
- Refreshments (cold and hot drinks) were provided free of charge at the service. Patients had access to nearby cafes and restaurants, should they wish to use them.

Patient outcomes

- Managers monitored the effectiveness of care and treatment and used the findings to improve them.
- The registered manager (scan practitioner) was responsible for governance and quality monitoring.
- We saw the service monitored the number and nature of scans undertaken, the number of return and repeat scans, and referrals made to third party healthcare providers.

Competent staff

- The service made sure staff were competent for their roles.
- The scan practitioner had undertaken training provided by the manufacturer to competently use the ultrasound equipment.
- The scan practitioner was a registered midwife, and held diagnostic training certificates; having practised in both NHS and private maternity, ultrasound and diagnostic environments before launching the service. She had also completed counselling and bereavement qualifications.
- The scan practitioner undertook regular self-directed and formal continuing professional development training. This included training around BMUS guidance, and they had attended national conferences about ultrasound practice.

Multidisciplinary working

- There were referral pathways to other agencies in place for staff to follow to benefit patients.

Good

Diagnostic imaging

- If a possible anomaly or concern was detected, staff told us that records could be shared with third party healthcare professionals, with the patient's consent.
- We saw evidence of referrals that had been made to hospital early pregnancy assessment units and GPs.
- The service had an up to date protection of vulnerable adults and children safeguarding policy; which contained the contact details of local authority safeguarding teams. Staff were aware of referral procedures and their reporting responsibilities.

Seven-day services

- Services were supplied according to patient demand. This meant the location were not necessarily open seven days a week; and services were typically provided four days per week, including Saturdays.

Consent and Mental Capacity Act

- Staff understood the importance of obtaining informed consent, and when to assess whether a patient had the capacity to make decisions about their care.
- Women's consent to care and treatment was sought in line with legislation and guidance. Women were required to complete a consent form prior to undergoing ultrasound scanning. Consent forms were tailored to specific scans. The scan practitioner told us that if potential concerns were identified, these would be discussed with the patient prior to the scan being carried out.
- The service did not have a consent and mental capacity act policy for staff to follow. However, we saw that the practitioner had attended consent training, which included training about mental capacity and deprivation of liberty safeguards.
- Since opening in February 2017, we saw that the service had provided scans to four patients under 16 years of age (all of whom were aged 15 years of age at the time scans were conducted). The scan practitioner was trained to safeguarding level three for children and young people, and clearly understood and could reiterate Gillick competence. We saw that the service had compiled a spreadsheet detailing the circumstances in which patients under 16 years of age had attended the service. For example, it described who had accompanied these patients to their appointment; in each case we noted that someone with parental responsibility had been present. To strengthen the approach, we suggested that the service should consider using a specific consent form for patients under 16 years of age, on which the scan practitioner could indicate that the Gillick test had been performed. Following our inspection, the service provided evidence that this had been implemented.

Are diagnostic imaging services caring?

Good

We rated the caring domain as **good.**

Compassionate care

- Staff cared for patients with compassion. Feedback from patients confirmed that staff treated them well and with kindness.
- The scan room afforded patients privacy and dignity, and confidential conversations could not be overheard by others using the service.
- During the inspection we spoke to six patients, and their companions. Patients and their companions we spoke with were very positive and complimentary about the service; for example, they described it as "brilliant" and "excellent". Some also commented they had returned after using the service during a previous pregnancy, because it was "so good".
- During our inspection, we observed staff were warm, kind and welcoming whey they interacted with women and their companions.
- We reviewed written feedback from over 140 women who had used the service. We saw women were very positive about the services provided. They said the service was "fantastic", "incredible", "warm and welcoming", "friendly", "kind", and they were "made to feel at ease". No negative feedback was observed.
- In line with their terms and conditions, the service took a non-refundable deposit at the time of booking.

However, if a patient cancelled their appointment due to pregnancy loss, the service voluntarily arranged to refund the deposit money; and we saw evidence of this.

- The service provided complementary repeat sexing/ gender scans if the baby's sex could not be determined at the time of appointment; and we saw evidence that the service had done so on 12 occasions in the November 2017 to November 2018 reporting period.

Emotional support

- Staff provided emotional support to patients to minimise their distress.
- The scan practitioner had been trained to deliver challenging news. They had a level two certificate in counselling concepts, and an additional counselling certificate in pregnancy loss and child bereavement (accredited by the NMC). The scan practitioner told us that should challenging news need to be delivered, this would take place in the scan room; and the patient would be counselled for as long as necessary. Staff said patients awaiting appointments would be informed of delays, if required.
- The scan practitioner said that should a possible anomaly be identified, and a referral to an antenatal care provider need to be made, that they always offered to call ahead for the patient; with their consent. For example, the scan practitioner described they would call the hospital early pregnancy assessment unit to refer the patient and reiterate their possible findings. The practitioner would then give the patient a written report and (if applicable) scan images to take along with them. This, the scan practitioner said, helped limit the patient's distress and provide a continuity of care.
- We observed written feedback from a woman who had used the service and had received challenging news. The woman described that the scan practitioner was "empathetic" and "so helpful". The woman said the practitioner allowed sufficient time for her to process the information received, and clearly explained what she needed to do next. The woman described that, despite the unexpected outcome, the service was "incredible".
- We also saw feedback from women who had previously experienced pregnancy loss, and had utilised the service during a subsequent pregnancy (predominantly for early pregnancy reassurance scans). They described the scan practitioner as "reassuring" and "very good at putting you at ease".
- During our inspection, we observed a woman attending for an early pregnancy reassurance scan, following a previous pregnancy loss. We saw the practitioner was reassuring and comforting when conducting the scan, and spent additional time answering questions the woman and her partner had about the current pregnancy.

Understanding and involvement of patients and those close to them

- Staff involved patients and those close to them in decisions about their care and treatment.
- During our inspection, patients we spoke with understood the nature of the ultrasound scans to be undertaken, and what would be involved. We saw that the scan practitioner appropriately communicated the limitation of services provided (for example, she noted that the scan was "just a moment in time") and stressed the importance of adhering to NHS maternity pathways. We observed patients were clearly informed of costs, and when and how they would receive their scan results.
- During our inspection, we observed the scan practitioner performing scans and saw the practitioner avoided jargon, communicated to women (and their companions) in a way they could understand, allowed sufficient time for questions, and sufficiently answered these.
- We saw the service sought feedback from patients about the quality of service they had received.
- Written feedback from women who had used the service described they were given ample time during appointments. For example, they explained the scan practitioner was "very patient" and "at no time did we feel rushed". Women were also very positive about having their questions answered, and the depth of information given. For example, they said the scan

practitioner "spent a lot of time with us explaining the different parts of the scan", "took her time to show us every part of baby", "talked through everything", and "spent time showing and explaining everything".

- The service encouraged women to bring along friends and family members (including children) to their ultrasound scan, if they so wished. During our inspection, we saw women were accompanied by various companions; such as, their partner, siblings, and parents. We saw all companions were made to feel welcome and included in the experience; and benefitted from the large wall mounted monitor in the treatment room. This was reflected in written feedback from women who described the service as "very accommodating". Many women also described how their companions had been made to feel involved in the experience. For example, "our 10-year-old daughter was included in the process", "gave my three-year-old a picture of the scan", and "we even took both sets of grandparents along to the gender scan who loved it".

Are diagnostic imaging services responsive?

Good

We rated the responsive domain as **good.**

Service delivery to meet the needs of local people

- The service planned and provided services in a way that met the needs of local people.
- The environment was appropriate for the service being delivered and was patient centred. There was a comfortable reception and waiting area, an accessible bathroom, access to free refreshments (hot and cold drinks), entertainment (magazines and radio), and there was adequate seating in the waiting area and scan room.
- The service was conveniently located in Wakefield town centre, and served by good public transport (rail and bus) links. Off street and pay and display car parking was available nearby.
- Information about services offered at the location were accessible online.
- The service was flexible to meet patients' needs, offering appointments after working hours during the week, and at weekends (on Saturday's).

Meeting people's individual needs

- The service took account of patients' individual needs.
- The service helped to ensure that women had sufficient time to ask questions by allocating different appointment time slots depending on the type of ultrasound scan and services requested. These typically ranged from 20 to 40 minutes. Women were also asked to attend the service earlier than their appointment time to complete paperwork; and to discuss any concerns they might have.
- Staff told us that they welcomed enquiries and queries, and would happily answer women's questions before booking, during their scan, or at any time after scans had been conducted.
- Staff told us that there was no provision of information in any language other than English. Staff said they would be happy for patients' friends or family members to attend appointments to translate, if required. This was not in line with best practise guidance. However, staff acknowledged that this would not be appropriate if they were concerned the patient was a vulnerable adult, lacked capacity to consent, or was under 16 years of age.

Access and flow

- People could access the service when they needed it.
- Women were offered a variety of appointment dates and times at booking. Women were able to book appointments via an online booking portal, using a social media messenger service, or by telephone, email, or in person.
- The service's online booking system (database) could be securely accessed by the business manager and scan practitioner. This, they said, enabled the service to be flexible in terms of their ability to plan appointments and deliver the service. They said the service was by appointment only, to minimise waiting times, and we saw gaps allocated at intervals between appointments to account for potential run-over.

Good

Diagnostic imaging

- The service opened according to patient demand, and typically operated three to four days per week; including on Saturday's. The service therefore had capacity to extend service provision as and when the need arose.
- In the 12 months prior to our inspection, no planned appointments were cancelled or delayed for a non-clinical reason; such as breakdown of equipment. The service did not have a waiting list.
- Patients we spoke with at the inspection were positive about the availability of scans, and said that they had received suitable appointments in a timely fashion. We also saw this reflected in written feedback we reviewed.

Learning from complaints and concerns

- The service treated concerns and complaints seriously, and had systems in place to investigate them and learn lessons from the results, and share these with all staff.
- The service had an up to date complaints and client feedback policy, which outlined procedures for accepting, investigating, recording and responding to local, informal, and formal complaints about the service.
- Patients or their representatives could provide feedback, raise a concern, or formally complain in person, by telephone, or by email or letter. The service did not display information about how to raise a complaint or concern in the clinic. However, information about how to complain was contained on the service's website, and was also detailed on consent forms.
- The service did not receive any informal or formal complaints in the reporting period November 2017 to November 2018.
- We saw that the service actively encouraged patients to provide feedback and raise any concerns they might have; and patients were able to leave reviews of the service on open social media platforms.
- Staff told us that that they regularly reflected on information and feedback gathered from patients, which assisted them in improving the quality of care and service delivery. For example, the service had launched a new range of merchandise ('heart beat bears').

Are diagnostic imaging services well-led?

Good

We rated the well-led domain as **good.**

Leadership

- Managers in the service had the right skills and abilities to run a service providing high-quality sustainable care.
- The leadership team was made up of the registered manager (scan practitioner) and business manager. No additional staff were employed by the service, and the service did not utilise any bank or agency staff.
- The scan practitioner was a registered midwife with over 20 years' experience, who had performed ultrasound scans as part of her extended midwifery role for over eight years before launching Early Days Baby Scan Ltd.
- The business manager had been responsible for managing and leading departments in the public and private sector before launching Early Days Baby Scan Ltd.

Vision and strategy

- The service had a vision for what it wanted to achieve and workable plans to turn it into action, which it developed with staff and patients.
- The service's aims and objectives were to "provide a safe and welcoming environment", and to "deliver a professional and caring additional pregnancy ultrasound service".
- We saw the service regularly sought feedback from patients, and monitored the marketplace and emerging technologies to ensure they offered a quality and competitive service.

Culture

Good

Diagnostic imaging

- Managers promoted a positive culture, creating a sense of common purpose based on shared values.
- As a small family run business, staff were in constant contact with each other throughout the working day. This, they said, facilitated good communication and enhanced the service provided to clients.
- Staff clearly marketed the service as an additional ultrasound facility, and were passionate about the quality of service they delivered.

Governance

- The service systematically improved service quality and safeguarded high standards of care by creating an environment for excellent care to flourish.
- The registered manager (scan practitioner) was the service lead for governance. Staff were clear about their roles and understood their responsibilities.
- The service had an up to date quality management policy and procedure. This described that the service measured quality through analysis of client feedback, service improvements, client safety record, and effectiveness of care received by clients; and we saw evidence that this was being undertaken.
- The service had an up to date notification policy and procedure for external reporting.
- All staff had DBS checks in place.

Managing risks, issues and performance

- The service had good systems in place to identify risks, plan to eliminate or reduce them, and cope with both the expected and unexpected.
- There were up to date risk assessment, and health, safety and environment policies and procedures in place.
- We saw the registered manager had undertaken a service risk assessment, which was due for renewal February 2019. The assessment detailed risks associated with business activities and potential environmental hazards, current controls to mitigate these, and actions to be taken.

Managing information

- The service had policies and procedures in place to promote the confidential and secure processing of information held about patients.
- Consent forms stated information was processed and used by the service in line with current data protection laws, and patients could opt in or out of having their scan images used for promotional purposes. Consent forms also contained a statement that included the terms and conditions of the services being provided, and method of payment of fees.
- Records were stored securely. The service was paper lite and mainly used a secure electronic database to create and share patient information. Where paper was used, the completed form was scanned onto the patient electronic record then securely destroyed.
- The service had an up to date policy for the creation, management, handling and storage of records and information; which detailed Duty of Candour responsibilities.
- The service was registered with the Information Commissioner's Office (ICO) and held a current certificate relating to this registration.

Engagement

- The service engaged well with patients and staff to plan and manage services.
- The service had performed extensive research into the demographic of the population and other services in the area to establish whether provision of the service was appropriate.
- We saw that the service actively encouraged patients to provide feedback; and patients were able to leave reviews of the service on open social media platforms. Staff told us that that they regularly reflected on information and feedback gathered from women and their companions to improve quality of care and service delivery. For example, the service had expanded its range of purchasable baby items.

Learning, continuous improvement and innovation

- The service was committed to improving services by learning from when things went well or wrong, and promoting training, research and innovation.

Good

Diagnostic imaging

- The registered manager (scan practitioner) was trained to competently use the ultrasound equipment; and was committed to learning and continuous development. They said the service was greatly enhanced by using current ultrasound technology.
- Although not practising under the qualifications, the scan practitioner was registered as a qualified midwife with the NMC. They also held study certificates in obstetric ultrasound measurements, and in pelvic ultrasound for reproductive medicine.
- The scan practitioner had recently attended national conferences about ultrasound practice.

Outstanding practice and areas for improvement

Areas for improvement

Action the provider SHOULD take to improve

- The service should consider amending consent forms in line with PHE guidance.
- The service should consider using a specific consent form for patients under 16 years of age, to evidence use of the Gillick test.