

Baby Grows Scan Clinic Limited

Baby Grows Scan Clinic Limited

Inspection report

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This report describes our judgement of the quality of care at this service. It is based on a combination of what we found when we inspected, information from our ongoing monitoring of data about services and information given to us from the provider, patients, the public and other organisations.

Ratings

Overall rating for this location

Inadequate



Are services safe?

Inadequate



Are services effective?

Inspected but not rated



Are services caring?

Good



Are services responsive to people's needs?

Requires Improvement



Are services well-led?

Inadequate



Summary of findings

Overall summary

We had not previously inspected this service. We rated it as inadequate because:

- The service did not provide or monitor mandatory training. Facilities were not designed to meet the needs of all women. Equipment was not always used appropriately to keep women safe. Staffing was not always enough to meet the needs of women. Care records were not detailed. Staff did not assess risk to women including infection risk was not always controlled well. The service did not have processes in place to identify and record incidents.
- The service did not provide good care and treatment. Managers did not monitor the effectiveness of the service or make sure that staff were competent.
- The service did not always take account of individual needs.
- The service did not meet the needs of all people because of the location. The service did not make it easy for people to follow a complaints process.
- Managers did not run services well because detailed policies were not available and there were no systems for outcome monitoring.

However:

- Staff knew what to do in an emergency.
- Staff worked well together for the benefit of women, explained information clearly and provided information through the website on how to lead healthier lives.
- Staff treated women with compassion and kindness and respected their privacy and dignity.
- The service offered appointments at times to suit women. They made it easy for people to book appointments at short notice.
- The service received positive feedback from those who used it.

Following this inspection we served the provider a Warning Notice under Section 29 of the Health and Social Care Act 2008. The warning notice told the provider they were in breach of Regulations 12 and 17 and gave the provider a timescale to make improvements to achieve compliance. The principles we use when rating providers requires CQC to reflect enforcement action in our ratings. The warning notice identified concerns in the safe and well-led domain. This means that the warning notice we served has limited the rating for safe and well-led to inadequate.

Summary of findings

Our judgements about each of the main services

Service	Rating	Summary of each main service
Diagnostic imaging	Inadequate 	

Summary of findings

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Summary of this inspection

Background to Baby Grows Scan Clinic Limited

Baby Grows Scan Clinic Ltd was a service providing ultrasound scans to pregnant women from 6 weeks gestation through to term. The aim and purpose of the service was to provide women and their families with reassurance and early bonding opportunities with their unborn baby. The service operates in the Leadgate area of Consett, County Durham.

The service had a registered manager in place since November 2021. The registered manager was also a fully trained midwife and sonographer. At the time of inspection there was a volunteer sonographer assistant also in place available to work Saturday mornings and two evenings per week. The service offered flexible appointments to meet individual's needs.

The service provided a range of ultrasound scans including early pregnancy, 2D reassurance scans, gender scans and 4D scans for young people aged 16 to 18 and women aged 18 upwards. It was registered to provide the regulated activity of diagnostic and screening procedures.

This service was inspected on the 10th February 2023. The service had not been inspected before. The service is registered with CQC to undertake the regulated activity of diagnostic and screening procedures.

How we carried out this inspection

The team inspecting the service consisted of a CQC lead inspector and an inspector. The inspection was overseen by an inspection manager.

The inspection was announced at short notice to ensure the service was operational on the day of the visit and to allow for observations of routine practice.

During the inspection visit the inspection team inspected all 5 of the key questions, safe, effective, caring, responsive and well led and rated four of these ('effective' is not rated for diagnostic and imaging services).

The team spoke to the registered manager, the volunteer sonographer assistant, 2 women who had attended the service recently and had used the service on more than one occasion. One scan procedure was observed. Policies, procedures and other documents relating to the delivery of the service were reviewed.

The suitability of environment and facilities were looked at.

The suitability of the website for Baby Grows Scan Clinic Ltd was reviewed.

You can find information about how we carry out our inspections on our website: <https://www.cqc.org.uk/what-we-do/how-we-do-our-job/what-we-do-inspection>.

Summary of this inspection

Areas for improvement

Action the service **MUST** take is necessary to comply with its legal obligations. Action a service **SHOULD** take is because it was not doing something required by a regulation but it would be disproportionate to find a breach of the regulation overall, to prevent it failing to comply with legal requirements in future, or to improve services.

Action the service **MUST** take to improve:

- The service must revise the training policy to include chaperone training, scan machine training, levels of safeguarding training required by staff according to role. The policy must also include frequency of all mandatory training specific to each subject with a clear process for review (Regulation 12 (1)).
- The service must develop a clinical risk assessment policy. This policy must outline what would constitute a risk, risk assessment at the time of taking a booking, review of risk during a woman's care, recording of risk. This must include exclusion criteria (risk circumstances preventing women accessing the service) along with circumstances that should be identified and reported as clinical incidents. (Regulation 12 (1)).
- The service must have a written standard operating procedure for staff to follow if an anomaly is identified during a scan (Regulation 12 (1)).
- The service must ensure infection prevention and control policies are in place and procedures aligned to current best practice guidelines. The service must evidence cleaning records of toilet facilities are checked, the appropriate decontamination process of transvaginal probes, a clinical and non-clinical waste removal process with details of any contractual arrangements (Regulation 12).
- The service must ensure ultrasound transmission gel is used in line with manufacturer recommendations and UK Health Security Agency Guidance (2022) (Regulation 12).
- The registered manager must complete level 3 safeguarding training for adults and children and ensure that the safeguard policy clearly states who the named safeguarding lead is (Regulation 13).
- The service must ensure there is a clinical governance policy in place. This policy must describe a structured framework to support the delivery of good care that is aspired to. This must include a process for clinical supervision for all staff specific to role (Regulation 17).
- The registered manager must complete risk review with mitigating actions to reflect the location of the nearest sink within shared toilet facilities (Regulation 17).
- The service must create a more detailed health and safety policy. This must set out clear specific sections. This must include guidance on operational audits, standard dated checklists to ensure safety of the building, specific descriptors of what would constitute an accident and incident, clear rationale for reporting of workplace accidents and incidents (Regulation 17).
- The service must have a clear process for carrying out DBS checks for staff at the point of recruitment to Baby Grows Clinic Ltd (Regulation 5).

Action the service **SHOULD** take to improve:

- The service should have a contingency plan for accessing mandatory training should the NHS provision cease to be an option for staff (Regulation 17).
- The service should update policies to ensure that there is clear guidance around display of domestic violence information and other support services available (Regulation 13).
- The service should align the existing lone working policy to refer specifically to Baby Grows Scan Clinic Ltd environment (Regulation 17).
- The service should ensure there is information accessible in a range of languages and braille (Regulation 9).

Summary of this inspection

- The service should ensure there is a visible complaint process available. The service should ensure the complaints policy and information providing regarding making a complaint advises customers to follow the appropriate route. (Regulation 17).
- The service should ensure there is a clear operational process to determine when a transvaginal scan would be offered (Regulation 12).






Our findings

Overview of ratings

Our ratings for this location are:

	Safe	Effective	Caring	Responsive	Well-led	Overall
Diagnostic imaging	Inadequate	Inspected but not rated	Good	Requires Improvement	Inadequate	Inadequate
Overall	Inadequate	Inspected but not rated	Good	Requires Improvement	Inadequate	Inadequate

Diagnostic imaging

Safe	Inadequate 
Effective	Inspected but not rated 
Caring	Good 
Responsive	Requires Improvement 
Well-led	Inadequate 

Is the service safe?

Inadequate 

We rated it as inadequate.

Mandatory training

The service did not provide mandatory training in key skills to staff. The provider did not have a policy to determine what training staff were expected to undertake.

At the time of inspection there was no staff training policy or process in place to monitor training. Following inspection, a policy was implemented by the registered manager, with an annual review date. However, the policy did not include the frequency of training or how the checks on timely completion of mandatory training would be carried out. The policy did not differentiate training needs of the sonographer role and assistant sonographer or chaperone role. The provider relied on staff being able to complete identified training through additional posts held within NHS services. There were no alternative options identified for sourcing training should this option cease to be available in the future.

The mandatory training was not comprehensive. It was completed in conjunction with requirements for other roles held in other employments and not tailored specifically to the roles within a keepsake baby scan service. The policy did not refer to training for the scan machine. The policy did not include chaperone training for the assistant sonographer role. The policy did not include first aid training. The mandatory training that had been completed for other roles was up to date. This was evidenced through copies of ESR (Electronic Staff Records) maintained where the employee had another NHS post.

Safeguarding

Staff did not understand how to protect women from abuse. Staff did not have up to date training on how to recognise and report abuse.

The provider had a safeguarding policy in place. However, it was not comprehensive and did not include the categorisations of abuse, processes or guidance on how to make a safeguard referral, safeguard contact details or state who was the safeguard lead for the location. The policy referred to a twenty-four-hour safeguarding helpline phone

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number but did not clearly stipulate the circumstances in which this number might be used. We saw a safeguarding flowchart within the policy, however, this did not state the point at which a safeguarding referral would be made. The policy did include reference to female genital mutilation (FGM) and PREVENT. The staff had not come across any such concerns but explained they would follow safeguarding processes.

The required level of safeguarding training was not clearly stipulated within the staff training policy and does not refer to the frequency for maintaining this training. Although the registered manager understood the level of safeguarding training that is required by the staff within the service.

The Registered manager was responsible for completing Level 3 safeguarding training, however, at the time of inspection we saw this training had been completed previously but had expired and there was a lack of clarity regarding where this training would be sourced from. Following inspection further training was identified through the Local Authority with an attendance date booked in for completion within a few weeks. The registered manager identified herself as the safeguarding lead and all staff were able to give examples of situations where individuals might be vulnerable and when safeguard alerts should be made. The volunteer sonographer assistant had also completed protecting children from sexual exploitation, safeguarding for people with a learning disability and PREVENT.

The safeguarding policy referred to the service carrying out appropriate checks for any potential and new colleagues joining the service. A Disclosure and Barring Service (DBS) check is required for people in paid and voluntary roles who may work with children and vulnerable people. The policy did not state what these checks would be, how they would be carried out and in what time frame.

Staff did not follow safe procedures for young people attending the service as there was no formal process in place for checking the age of women attending and therefore no way to verify that a person attending for a scan was over 16 years of age.

The safeguarding policy did not clearly identify a range other services available for support.

Support for domestic violence was recognised by staff and posters were displayed within the private areas of the toilet facilities.

Cleanliness, infection control and hygiene

The service did not always control infection risk well. Staff did not have access to hand washing facilities in the clinic area to protect women, themselves and others from infection. There were no cleaning records for shared facilities.

There were no hand washing facilities available within the clinic room or the service - the nearest hand washing facilities were external to Baby Grows Scan Clinic Ltd environment along a corridor through a set of double doors and a further door into shared toilet facilities. There was an infection prevention and control policy in place, however, this did not reflect the restricted availability of hand washing facilities and did not identify any specific risk mitigation due to the location of the nearest hand washing facilities. It did not clearly state the frequency of the need for hand washing rather than use of hand gel. The policy identified a hand hygiene audit would be completed at least annually. There was a separate hand hygiene audit sheet which detailed hand rub and hand wash techniques that evidenced audits had taken place.

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There were no cleaning records made available by the external cleaning company responsible for the cleaning of the shared toilet facilities. There was a cleaning policy in place that identified the registered manager would carry out daily toilet checks. The policy did not reflect arrangements to check formal cleaning records for the shared facilities which housed the only hand washing facilities available. There was no reassurance that whilst the toilet facilities looked clean, they had been cleaned with appropriate cleaning solutions to minimise infection risk.

At the time of inspection there was no documented process or policy to detail cleaning of trans-vaginal probes. Following the inspection, a probe decontamination log was implemented by the registered manager with immediate effect and evidence of the cleaning policy provided. The cleaning policy referred to appropriate cleaning guidance for the trans-vaginal probe through a provision of web links to the manufacturers websites that included the cleaning guidance. Protective covers would be removed and placed in the appropriate bin whilst antibacterial wipes would be used to clean the probe.

Clinical areas were clean and had suitable furnishings which were impermeable and well-maintained. Clinical areas were cleaned in between each appointment with appropriate wipes and a deep clean was performed at the end of each day. There was a small amount of children's play equipment available that was wiped clean in between each use. The cleaning checklist identified each area to be cleaned and when. Cleaning records for the service environment were observed and demonstrated that all areas were cleaned regularly. Staff were observed to clean equipment after patient contact.

The sonographer wore appropriate personal, protective equipment (PPE) during each scan procedure and there were enough supplies of PPE. There was a COVID screen on each consent form. At the time of inspection, it was identified that each appointment slot was one hour so there would not be more than one family group in attendance at the clinic at a time

We saw hand gel available in each area of the service and visitors were asked to gel their hands on arrival. Staff were observed to gel their hands between activities and reported using hand gel on entering and exiting the service.

There were appropriate hand washing posters displayed in the shared toilet facilities.

Environment and equipment

The design, maintenance and use of facilities, premises and equipment did not always keep people safe. Staff were trained to use equipment. Staff did not manage clinical waste well.

The service did not have suitable facilities to meet the needs of all women and families. The service is located within a larger building also used by other services. The toilets were shared facilities with other units within the building along the corridor.

The specific Baby Grows Scan Clinic Ltd environment was observed to be visibly clean, bright and welcoming. The registered manager recognised that the main shared entrance to the building was dated and in need of updating.

The scan machine was leased to the service with a maintenance policy and contact details available should the machine breakdown. Staff carried out daily safety checks of specialist equipment as per the manufacturer's guidance.

The service had a first aid kit in date and the registered manager reported checking this on a regular basis. However, checks were not recorded, therefore we were not assured that this equipment had been checked. A check list was implemented immediately following inspection and the health and safety policy identified monthly checks.

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The service used ultrasound transmission gel decanted from larger containers to smaller bottles. There were no labels on the bottles to identify the date of opening. Guidance from the UK Health Security Agency, Good infection prevention practice: using ultrasound (2022) states that sterile and non-sterile gels should not be decanted from larger containers and bottles should be labelled with the date of opening and disposed of after one month or on the expiry date, whichever comes first.

Staff did not dispose of clinical waste safely. The providers health and safety policy briefly stated the requirements under section 34 of the environmental protection Act 1990 to dispose of waste in accordance with the Act. There were no clear guidelines evidenced to determine the difference between clinical and non-clinical waste. However, the registered manager told us that waste was taken away by the site manager as part of their role. We were told that there was no clinical waste generated although if circumstances changed there was a service provided by the local council that would be used.

Assessing and responding to patient risk

Staff did not clearly document risk assessments for each woman. Staff knew what to do when there was an emergency.

Staff did not consistently record risks for each patient when booking in or arrival, using a standard process. The registered manager explained that often on booking in a phone conversation would be had with a client and that any health concerns or risk issues may be picked up through this conversation. There was no clear section on the booking form to highlight any health concerns or risk issues and no policy linked with the booking form to support a clear process. The providers consent policy outlined a process for gathering risk information, there was no section on the form clearly identified as a risk information section. There was a section for other information where any risks would be included.

There was a risk of women attending very early on in pregnancy and re attending for repeat reassurance scans if there was no evidence of foetal heartbeat at the first scan. Without a clearly documented policy and process of when to refer on to statutory NHS services should there be concerns, we were not assured that appropriate actions would be taken to keep women safe. However, we saw one example of a situation where one woman had been referred on to the NHS services following no detection of foetal heartbeat.

There were no exclusion policies in place or a ceilings of care criteria. The provider told us they would accept all women. The registered manager was clear about providing a service that did not exclude people and wanted to offer a good experience for all possible client groups. Without clear policies in place there is no reassurance that care will not be provided when individuals should be redirected to appropriate NHS services. There was no policy to determine decision making process for a trans-vaginal scan to be offered as an alternative. However, there was detail on the website to explain when this option might be offered.

The registered manager was aware of NICE guidelines around early pregnancy scans and roles and responsibilities of the service provided at Baby Grows Scan Clinic Ltd. The website and consent form identified clearly that the service was in no way to be used as an alternative to routine NHS care and that all planned appointments should be attended.

The registered manager was experienced and able to identify other risk concerns that needed onwards referrals during scan procedures. There was a referral form evident for onwards referrals, however there was no policy to support

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completion of referral including such information as in what circumstances a referral may need to be completed, where referrals would be sent on to and in what timescale. The registered manager was also clear in her responsibilities around any follow up with clients and where her role ended, however, this was not clear through a supporting policy or pathways.

A policy and procedure were in place for dealing with emergencies. Staff were trained in basic life support and would follow an appropriate course of action should an emergency arise. There was also knowledge of where the nearest (Automated External Defibrillator) AED was located.

Staffing

The service did not always have enough staff with the right qualifications, skills, training and experience to keep women safe from avoidable harm and to provide the right care.

There weren't always enough staff to meet the needs of the women attending the service as there was not always chaperone cover available. The volunteer sonographer assistant was only available for a small number of hours each week and there were times that the registered manager would work alone. However, the registered manager would only book early pregnancy scans for a time when there was chaperone cover. Women known to be over 14 weeks could be booked anytime as an internal scan would not be required for these women.

Not all staff had a DBS in place specific to the service at the time of inspection.

There were no vacancies and no requirements for additional staff at the time of inspection. If the volunteer sonographer was not available at the time a chaperone was required, then an alternative appointment slot would be offered to ensure there was chaperone availability.

The registered manager told us there were plans to increase staffing once the service and business grew. There were plans to have a contingency for holiday cover as the business grew.

Records

Staff did not keep detailed records of women's care and diagnostic procedures. Risk was not clearly recorded. However, records were up to date, stored securely and easily available to all staff providing care.

Women would either ring or make contact through the website to book an appointment. Booking forms were completed over the phone at the point of booking an appointment which allowed for gathering basic information. We reviewed eight sets of patient records and saw risk information was not clearly recorded at the time of booking. There was no clear section for inclusion of any risk information, for example, repeated miscarriage or medical history, however this was included in the 'any other information' section. There was a specific section for allergies. There was no specific section for any special needs or adjustments required. We did see evidence on one form where an additional health issue had been noted down, however with no clear process there could be missed information that could impact the appropriateness of attending for a keepsake baby scan.

Information gathered was stored in a locked filing cabinet that the registered manager was always key holder for and kept keys on her person. This information would then be transferred to a password protected database and saved in quarters.

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Incidents

The service did not manage safety incidents well. Staff did not recognise and report incidents and near misses.

The service did not have a specific policy around incident management. There was a section relating to accidents and incidents within the health and safety policy. This highlighted the need to report accidents or incidents in order to keep the effectiveness of safety systems under review. This did not refer specifically to what would constitute an accident or incident requiring reporting. It did refer to hazards within the clinic and provided a process for reviewing any reported incidents occurring from hazards. Staff understood incidents to relate to any situation where first aid would be required or where somebody attending the clinic was harmed as a result of a hazard within the clinic. There was an accident and incident reporting book evident in the clinic. There had been no reports made.

Without a clear policy there was a risk that staff may not have a clear understanding of incidents to report and learning from any such incidents shared to mitigate further incidents.

The provider told us there had not been any incidents in the last 12 months. Onward referrals for concerns such as no foetal heartbeat were not reported as incidents. This did not give assurance that there was sufficient review of all safety systems in place including staff support or debrief in dealing with difficult situations.

Is the service effective?

Inspected but not rated 

Inspected but not rated.

Evidence-based care and treatment

The service did not always provide care and procedures based on national guidance and evidence-based practice.

Policies in place did not always reflect NICE guidance. National guidance was not followed around the storage of ultrasound transmission gels. There was no documented guidance around referral pathways to escalate concerns found during scan procedures. However, the registered manager was able to describe NICE guidance regarding processes to follow if there was no foetal heartbeat detected. There was written information provided regarding ALARA (as low as reasonably achievable) principles available on the website. ALARA means avoiding radiation that does not have a direct benefit to you, even if the dose is small. The British Medical Ultrasound Society (BMUS) safety statement was displayed on the clinic wall.

The registered manager was a member of recognised bodies including the Society of Radiographers (SoR). The service website provided links to a range of evidence-based information for women during pregnancy relating to the importance of maintaining healthy lifestyles.

Patient outcomes

Staff did not always monitor the effectiveness of care.

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The service carried out audits for hand hygiene. There were no other audits carried out at the time of inspection. There were no reviews in place to check quality of scans. There was no outcome monitoring to reflect the requirement for trans-vaginal scans, numbers of referrals on to NHS services or number of repeated appointments given in the event it was not possible to get a good image.

Satisfaction of women and families using the service was monitored through receipt of feedback forms and feedback provided on social media accounts.

Competent staff

The service did not make sure staff were competent for their roles. Managers did not appraise staff's work performance or hold supervision meetings with them to provide support and development.

There was no policy or process in place for ensuring supervision or peer review of the registered manager within the Baby Grows Scan Clinic Ltd environment. There was no clear plan for how re-validation with the Nursing and Midwifery Council would be achieved in the future.

The policy did not include additional training to enhance the service provision such as mental health, learning disability or autism awareness training. The policy did not reference any other linked policies, for example, there was no reference to the safeguarding policy to determine a clearer understanding of the requirements of different staff in relation to safeguarding training.

The registered manager supported the volunteer assistant sonographer to develop and planned to carry out annual supervision and review of the role. However, there was no policy in place to support this.

There was no system in place for peer review of scans at the time of inspection. The registered manager recognised that there was a need to develop a process for peer review and ongoing professional development for her own role.

The registered manager held appropriate professional qualifications as a midwife and sonographer and was up to date with re-validation.

The registered manager had completed additional training in perinatal mental health, diabetes and hypoglycemia through other roles that she had held. The volunteer sonographer assistant had also completed additional awareness training in autism and learning disabilities as part of other roles that she held.

There was an induction policy in place for all new staff to have a full induction tailored to their role before they started work. There was a checklist included with this policy. There was evidence of a signed checklist with all areas of induction completed for the volunteer assistant sonographer.

Multidisciplinary working

Staff supported each other to provide care.

The registered manager and assistant worked well together.

The registered manager was able to identify other services that were available to refer women onto and had a format in place for documenting rationale to refer on to the local maternity assessment units as needed. We saw evidence of a woman whom had been referred on. This had been documented in a standard format using SBAR (situation, background, actions, recommendations).

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Seven-day services

Services were available to support timely patient care.

Appointments were available at times that met the needs of women and their families. The registered manager worked flexibly to meet women's needs and recognised that by living locally appointments could be offered at short notice.

Health promotion

Staff made information available on practical support and advice to lead healthier lives.

The service had relevant information promoting healthy lifestyles and support on the website. However, there were no leaflets available within the clinic environment.

Consent, Mental Capacity Act and Deprivation of Liberty Safeguards

Staff supported women to make informed decisions about their care. They followed national guidance to gain women's consent.

We reviewed the consent policy. This policy outlined the process for gaining consent. This policy stated that those under 16 years of age and those unable to consent would not be eligible for an ultrasound examination.

The website provided details of the scans available and the number of weeks each of these scans would be available from. Women had sufficient information provided through the website to be able to make an informed decision.

Consent was gained using consent forms. There was a separate consent form available for each type of scan. Each consent form detailed what would happen during the scan and what would not happen and when there would be a need to refer back to NHS services. Each consent form made it clear that the scans provided by Baby Grows Clinic Ltd did not replace NHS scans or any part of the Foetal Anomaly Screening process.

The consent form was completed on arrival and the registered manager reviewed the form with each woman attending once in the scan room prior to the scan taking place. Staff made sure women consented to treatment based on all the information available. The registered manager did not carry out formal checks of ID to confirm a person's age and could not provide reassurance that no scans would be carried out for under 16's.

Staff had completed Mental Capacity Act training.

Consent forms were stored securely in the women's records.

Is the service caring?

Good 

We rated it as good.

Compassionate care

Staff treated women with compassion and kindness, respected their privacy and dignity, and took account of their individual needs.

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Staff were discreet and responsive when caring for women. Women told us staff took time to interact with women and those close to them in a respectful and considerate way. Staff were warm and responsive to individuals needs ensuring there was enough time in each appointment to achieve the aims of the appointment. For example, if a good view was not possible of an unborn baby at first, time and patience was given to trying to ensure the best possible view whilst ensuring women continued to be comfortable. Additional re-scan appointments were arranged free of charge if it had not been possible to get a clear scan due to baby's position.

Women told us staff treated them well and with kindness and made them feel very at ease.

Staff followed policy to keep patient care and treatment confidential. The registered manager explained that any women making email enquiries for bookings would be emailed back first to clarify suitable contact details and times in order to avoid awkward phone calls in the case that women may not have shared their news with others whom they may be in company with when receiving return calls.

Staff understood and respected the individual needs of each patient and showed understanding and a non-judgemental attitude when caring for or discussing women with mental health needs. Staff did not wish to exclude anybody from using the service and would provide people with the details of other organisations such as local mental health organisations for additional support.

Staff understood and respected the personal, cultural, social and religious needs of women and how they may relate to care needs.

Emotional support

Staff provided emotional support to women, families and carers to minimise their distress. They understood women's personal, cultural and religious needs.

Staff gave women and those close to them help, emotional support and advice when they needed it. A full hour was given for each appointment time to allow for time to provide emotional support as and when needed.

Staff described how they would support women who became distressed in an open environment and help them maintain their privacy and dignity. The layout of the service allowed for personal space within the scan room in a comfortable environment. The hour appointment slots allowed individuals and families to be able to leave in their own time and were able to exit the service without needing to go back into the waiting area or pass others on the way out.

Staff understood the emotional impact that a person's care, treatment or condition had on their well-being and on those close to them.

Understanding and involvement of women and those close to them

Staff supported women, families and carers to understand their condition and make decisions about their care and treatment.

Staff made sure women and those close to them understood their condition and procedures. Women stated that all procedures were fully explained throughout the appointment. We observed a scan procedure where a full explanation of the process was given throughout the appointment.

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Staff talked with women, families and carers in a way they could understand. Staff were observed to ask questions regarding women's NHS care plans and explained the appropriateness of having additional scans at different stages throughout the pregnancy. Appropriate and sensitive language was used.

Women and their families could give feedback on the service and their treatment and staff supported them to do this. Feedback slips were given out with the scan images and there was the opportunity to provide feedback via the social media pages.

Staff supported women to make informed decisions about their care.

Feedback from women both during the inspection and via social media accounts was all positive and very complimentary of the service provision. No negative feedback had been received.

Is the service responsive?

Requires Improvement 

We rated it as requires improvement.

Service delivery to meet the needs of local people

The service planned and provided care in a way that met the needs of local people and the communities served.

The service advertised appointment availability on a 7 day a week basis including evening appointments to allow for women to attend at a time that suited them and their families.

There was ample car parking and signage visible from the car park, directing people to the correct entrance. The car park was secured at night and customers would ring on arrival for the gate to be opened using a key fob that could be operated through the window of the clinic. On entrance to the main building there was a sign giving specific instructions for customers to gain access for their appointment. There was level access to the building, however, the clinic was accessed by a flight of stairs, with no lift facilities available in the building. The registered manager or assistant sonographer would greet women and families in reception, for each appointment.

Meeting people's individual needs

The service was not inclusive and did not take account of women's individual needs and preferences. Staff did not make reasonable adjustments to help women access services. However, they directed women to other services where necessary.

The service did not have a policy for equality, diversity and inclusion.

The service did not have a policy which outlined how the service adapts to and meets the needs of those with mental health needs or learning disabilities.

The service did not have facilities to meet the needs of people with sight or hearing problems. There was not a hearing loop and no information available in accessible formats.

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The service was provided on the first floor of a building with no lift access.

The provider was unable to provide any examples of reasonable adjustments that were made for women using the service.

The registered manager identified that interpreter services would be contacted for interpretation over the phone should the need arise. There was no clarification provided regarding the sourcing of an interpreter and whom would be responsible for this. There was no additional information available in alternative languages or braille.

Staff had completed training on equality, diversity and human rights, learning disabilities training and mental health awareness. Staff identified services to refer people to for additional mental health support. Staff explained they would talk to women requesting repeat reassurance scans and consider advising they seek support from a mental health support service.

Information was available on the website explaining clearly when it would be appropriate to offer a scan and in what circumstances a woman would be advised to speak to their NHS midwife first.

Access and flow

People could access the service when they needed it. They received the right care and their results promptly.

Appointments were available seven days a week and there were no waiting times. Feedback reviewed on the website identified that women had been able to book at short notice for reassurance scans on the same day. The registered manager reported that there were no appointments that had not been attended following booking. The registered manager had not had to cancel any appointments once booked, in the last 12 months.

The appointment slots were booked an hour apart to ensure that women and families did not have to wait in the clinic waiting area unsupervised whilst scans were ongoing in the scan room.

Learning from complaints and concerns

It was not easy for people to raise concerns about care received. The service recognised the need to treat concerns and complaints seriously and investigate them. The service would include women in the investigation of their complaint.

There was no complaints procedure displayed in the service environment or included on the website. A slip is placed into each pack a client receives with their scan pictures asking for feedback regarding the service. The service had a complaints policy in place which outlines how to make a complaint, how women would be involved and timescales for responding to complaints. However, the policy also referred to complaints being forwarded to the CQC should there be no resolution by the service manager. This would not ensure that complaints are dealt with. There was no information regarding approaching an alternative service such as an Independent Sector Complaints Adjudication Service (ISCAS) or mediation service. The provider told us they had received no complaints.

Is the service well-led?

We rated it as inadequate.

Diagnostic imaging

Leadership

Leaders did not manage the priorities for the service well.

The registered manager met the Fit and Proper Persons Requirement (FPPR) (Regulation 5 of the Health and Social Care Act (Regulated Activities) Regulations 2014). There was one additional member of staff employed on a voluntary basis until the business becomes more fully developed and opportunities created to develop additional paid roles. The registered manager described the priorities for the service to be able to offer something that would enhance the statutory NHS maternity support. As the service was relatively new there were no plans identified to develop staff skills or formulate succession planning to support the continuation of the service in the future, but this was to be considered as the service developed.

Vision and Strategy

The service did not have a clear vision for what it wanted to achieve. It did not have a strategy to turn it into action.

The registered manager had a view of the role of the service alongside statutory service provision. However, there was no credible statement of vision and guiding values. Without clearly documented ceilings of care there was no reassurance of how boundaries would be maintained. There was a statement of purpose and a clear user-friendly website detailing the role of the service provision. However, this was not underpinned by detailed objectives or plans for sustainable delivery.

There was no documented business plan or strategy that supported day to day provision or a longer-term vision. The service was still relatively new and the focus for the first year had been to get established in the local area with a regular flow of women accessing the service. The registered manager was an experienced and knowledgeable clinician and wanted to use her background to be able to develop the service to meet needs that would enhance women's experiences of pregnancy. The registered manager was aware of women's needs during pregnancy and how this can be both an anxious and exciting time. The registered manager was able to reflect on the importance of women having the best care and support available to them during pregnancy.

Culture

Staff felt respected, supported and valued. They were focused on the needs of women receiving care. The service had an open culture where women, their families and staff could raise concerns without fear.

The registered manager received positive feedback from those who used services and told us they had not received any complaints. Two women we spoke with, had both attended following recommendations from others and had felt that the service provided an environment that gave them their own space and time. They found the registered manager to be very approachable and felt they would be able to raise any concerns.

During the inspection several areas of concern were discussed. These were acted upon quickly and the response was positive in making the appropriate changes required.

Governance

Leaders did not operate effective governance processes. Policies did not provide clarity about their roles and accountability.

Diagnostic imaging

Governance arrangements and purpose were unclear. There was a lack of systematic performance management. There was no supervision policy in place which did not provide assurance that practice was reviewed. There was no guidance regarding peer review for the scans carried out. There was no plan outlined for continuing professional development and re-validation. There was no formalised process for the supervision of the assistant sonographer role. The registered manager recognised that the first year of the service had focused on gaining business and the second year needed to focus on professional development and ensuring appropriate support and supervision was used.

There was no record keeping policy in place that clearly identified standards for record keeping. There was a privacy policy in place that referred to data retention. This did not include retention periods and destruction of data.

There was no exclusion or inclusion criteria identified for the service and no consideration of the need for this in relation to risk. Without clear criteria being specified there may be a risk that women may attend too early in pregnancy or whilst having additional scans such as extra growth scans. The registered manager was observed to explain an example of a situation where additional keepsake scans would not be appropriate if a woman was also in receipt of an NHS care plan for additional growth scans. Without a clear policy there was no governance to ensure that such information would be gathered and then acted upon accordingly.

There was a lone working section within the health and safety policy, however this did not outline clear processes specific to the environment and potential risks. There was no risk assessment to support lone working or identify when there may have been increased risks either to staff or women attending the service. The registered manager did identify the presence of a security team that operated 24 hours a day 7 days a week on the business park. This was referred to in the health and safety policy and a contact number included, however specific support that the team were able to offer was not made clear.

There was no operational governance process in place for oversight of the general building facilities including fire extinguisher checks and fire safety checks for the building, gas certificates and electrical safety certificates. The registered manager did explain that there was a fire safety test completed weekly within the building and was aware that the caretaker held all documents relating to the safety of the building. The certificates were all in date.

There was a health and safety policy in place. The health and safety policy comprised of a number of short sections including workplace (health, safety and welfare), work equipment scope and purpose, accidents and incidents, control of substances hazardous to health, waste management, lone working, fire safety and first aid. These sections did not all include sufficient detail and operational requirements pertaining to the specific functioning of Baby Grows Scan Clinic Ltd. Risk assessments were referred to but there was no clear guidance to identify which risk assessments needed to be carried out and in what timescales. There was evidence of risk assessments for slips, trips and fall hazards, display screen equipment, fire, hazardous substances and manual handling.

Management of risk, issues and performance

Leaders did not use systems to manage performance effectively. They did not have a policy to escalate relevant risks and issues and identify actions to reduce their impact.

There was little understanding of management of risks or issues. There was a referral and consent form in place for women booking into the service. There was no section on this form and no policy to support gathering of risk information from women. There was no exclusion policy in place. There was no policy detailing the process for onward referrals on finding concerns when carrying out scan procedures. The registered manager was able to explain the process and when an onward referral would be made and linked this with a knowledge of NICE guidance. There were no audits carried out. Reviews of images did not take place.

Diagnostic imaging

There was no incident reporting policy. Therefore, there was no guidance for staff on what incidents to report and how to monitor or review incidents. There was an incident / accident reporting book available to record incidents in. The provider did not support staff in escalating relevant risks or identify when additional peer support and review would be beneficial.

During the inspection it was identified that the volunteer did not have a DBS certificate in place for the role held at Baby Grows Clinic Ltd.

Information Management

Information systems were secure.

The service had a privacy policy which referred to requirements under the General Data Protection Regulation (GDPR) 2018. All staff completed information governance training. Records were kept in a secure locked filing cabinet and a password protected database. No information was provided to explain circumstances when women's information might need to be shared.

Engagement

The provider actively and openly engaged with women and staff to plan and manage services.

The registered manager engaged with women and families through the website and social media accounts. The women we spoke to who had used the service had become aware of the service through recommendations by others locally as the registered manager had a good reputation.

Learning, continuous improvement and innovation

All staff did not recognise that there was a need for continued learning and improvement of services.

There was minimal evidence of learning and reflective practices. The service was still being established and there were areas for improvement that the registered manager recognised during inspection and was keen to improve. There was a positive response to concerns raised at the time of inspection and some changes were implemented immediately.