Baby Ultrasound Clinic Sheffield Limited

Baby Ultrasound Clinic Sheffield

Inspection report

Unit 12
3 New Era Square
Sheffield
S2 4RB
Tel: 07809214190
www.babyultrasoundclinic.co.uk

Date of inspection visit: 10 June 2022
Date of publication: 12/08/2022

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	Inspected but not rated
Are services safe?	**Inspected but not rated**
Are services well-led?	**Inspected but not rated**

Summary of findings

Overall summary

This was a focused, announced inspection in response to specific areas of concern, we did not rate this service as we only inspected key lines of enquiry within the safe and well-led domains. The service had not been inspected or rated previously.

- Staff did not always have the right qualifications, skills, training, and experience to keep patients safe from avoidable harm and to provide the right care and treatment.
- The service did not provide mandatory training in key skills to staff or have a mandatory training policy in place to ensure training was completed regularly.
- The service did not always ensure that staff employed were recruited safely.
- Managers did not always ensure that premises and equipment were checked for safety and cleanliness.
- Staff did not always identify nor quickly act upon patients at risk of deterioration.
- Staff did not always recognise and report incidents and near misses.
- The service did not always coordinate care with other services and providers.
- Leaders and managers did not always understand and manage the priorities and issues the service faced.
- The provider did not have plans in place to cope with unexpected events.
- Leaders did not operate effective governance processes throughout the service. They did not use systems to manage performance effectively. They did not always identify and escalate relevant risks and issues nor take action to reduce their impact.

However:

- The service operated safeguarding processes and systems to protect people from abuse.
- Leaders were visible and approachable in the service for patients and staff.
- Staff felt respected, supported, and valued. They were focused on giving patients a positive baby scan experience. The service had an open culture where staff could raise concerns without fear.

Following our onsite inspection, we served the provider with a Warning Notice under Section 29 of the Health and Social Care Act 2008. The warning notice told the service that they needed to make significant improvements in their governance processes to ensure the quality and safety of services provided.

Summary of findings

Our judgements about each of the main services

Service	Rating	Summary of each main service
Diagnostic and screening services	Inspected but not rated	We did not rate this service at this inspection. Please see the overall summary above for more information.

Summary of findings

Contents

Summary of this inspection

Background to Baby Ultrasound Clinic Sheffield

Baby Ultrasound Clinic Sheffield is privately operated by Baby Ultrasound Clinic Sheffield Limited. The service registered with the Care Quality Commission in 2021 and has had the same registered manager in place since then.

The location is registered to provide the following regulated activities:

- Diagnostic and screening procedures.

The service had not previously been inspected.

How we carried out this inspection

The team inspecting the service comprised of a CQC lead inspector and an assistant inspector. The inspection was overseen by Sarah Dronsfield, Head of Hospital Inspection.

Our inspection took place on the 10th June 2022, using our focussed inspection methodology. The inspection was announced with short notice to ensure the service was operational on the day of our visit and enable us to observe routine activity. We looked at five sets of patient records and four staff files. We spoke with the Registered Manager, the receptionist, sonographer, observed an ultrasound scan and spoke with a person using the service.

We looked at complaints received by the service as well as general patient feedback. The provider had not recorded any incidents.

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.We did not rate this service at this inspection. Please see the overall summary above for more information.

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 provider must ensure staff receive support and training as is necessary to enable them to carry out the duties they are employed to perform. **(Regulation 18(2)(a))**
- The service must ensure that there is a system and process used to confirm that individuals, employed for the purposes of carrying on a regulated activity, satisfies the necessary requirements, and is monitored for completeness. **(Regulation 17(2)(a))**
- The service must have systems and processes in place to assess, monitor and improve the quality and safety of the service, for example, regular audits. **(Regulation 17(2)(a))**
- The service must ensure that when working with other organisations there are agreements in place to ensure staff have clear responsibilities and were held accountable for actions taken at other locations. **(Regulation 17(2)(a))**

Summary of this inspection

- The service must ensure that when working with other organisations there are agreements in place to ensure the safe and secure sharing of information. **(Regulation 17(2)(a))**
- The service must ensure that it has an escalation process in place in the event of recognising abnormalities during ultrasound scanning. **(Regulation 17(2)(b))**
- The service must assess risks to women's health before delivering keepsake scans. **(Regulation 17(2)(b))**
- The service must have a process in place to ensure staff are adhering to rescanning timeframes outlined in provider policy. **(Regulation 17(2)(b))**
- The provider must ensure incidents that affect the health, safety and welfare of people using services are recognised and reviewed and thoroughly investigated by competent staff, and monitored to make sure that action is taken to remedy the situation, prevent further occurrences and make sure that improvements are made as a result. **(Regulation 17(2)(b))**
- The service must ensure they have processes to assess, monitor and mitigate the risks relating to the health, safety and welfare of service users and others who may be at risk which arise from the carrying on of the regulated activity. **(Regulation 17 (2)(b))**
- The service must ensure that specialist machinery is frequently cleaned to prevent and control the spread of infections. **(Regulation 17 (2)(b))**The service must have a process in place to ensure that specialist machinery is frequently and robustly checked to ensure it is safe for use. **(Regulation 17 (2)(b))**
- The provider must ensure they have evidence that staff meet the professional standards which are a condition of their ability to practise or a requirement of their role. **(Regulation 17(2)(c))**

Action the service SHOULD take to improve:

- The service should consider implementing a tool to assess deterioration in women's health.
- The service should ensure they have a plan in place to cope with unexpected events to respond to unforeseen circumstances such as loss of power.
- The service should ensure that there are systems in place to ensure clinical waste is disposed of appropriately.

Our findings

Overview of ratings

Our ratings for this location are:

	Safe	Effective	Caring	Responsive	Well-led	Overall
Diagnostic and screening services	Inspected but not rated	Not inspected	Not inspected	Not inspected	Inspected but not rated	Inspected but not rated
Overall	Inspected but not rated	Not inspected	Not inspected	Not inspected	Inspected but not rated	Inspected but not rated

Inspected but not rated

Diagnostic and screening services

Safe	Inspected but not rated
Well-led	Inspected but not rated

Are Diagnostic and screening services safe?

Inspected but not rated

Mandatory training

They did not have a policy or process in place to make sure everyone completed training in key skills.

The service did not have a mandatory training policy in place.

Managers recorded mandatory training but were unable to monitor and alert staff when they needed to update their training as there was no policy in place to indicate when this was required.

However, the training staff had received met the needs of women and staff.

Safeguarding

Staff understood how to protect women from abuse but did not always have processes in place to identify safeguarding risks. Staff had training on how to recognise and report abuse and they knew how to apply it.

Staff received training specific to their role on how to recognise and report abuse. All staff received online training to level two for safeguarding adults and children. The registered manager was the safeguarding lead for the organisation and was trained to level 3.

Staff knew how to identify adults at risk of harm. The service had not had any safeguarding concerns; but staff told us how they would recognise signs of abuse and knew how to escalate concerns to external agencies.

There was a clear escalation process visible within the service with appropriate external contacts for staff to inform if there was a safeguarding concern when the registered manager was not present.

However, there was no process in place to assess safeguarding risks during the booking or consent process therefore, staff had no way of identifying whether potentially vulnerable women were safe if they did not attend the service.

Cleanliness, infection control and hygiene

The service did not always control infection risk well. Staff used equipment and some control measures to protect women, themselves and others from infection. They kept equipment and the premises visibly clean.

Clinical and waiting areas were visibly clean, however the provider had chosen soft furnishings in waiting areas which made them more difficult to clean between patients.

Cleaning records did not demonstrate that all areas were cleaned regularly as these did not include the ultrasound scanning machine, however cleaning schedules were kept up to date for general cleaning of the waiting and clinical areas.

Staff followed infection control principles including the use of personal protective equipment (PPE). We observed an ultrasound scan where the sonographer followed infection prevention and control principles and the receptionist regularly cleaned the communal waiting area throughout the day.

Environment and equipment

The design and use of facilities, premises and equipment kept people safe, however how they were maintained did not. Staff did not always manage clinical waste well.

The service had suitable facilities to meet the needs of women's families. The service consisted of a large waiting area which had allowed for seating to be socially distanced, was accessible, had an accessible toilet and large sonography room which was fully equipped to meet the needs of women and their families.

The service had facilities in place to dispose of clinical waste safely if required although this was not a routine part of practice. However, if they did need to dispose of clinical waste, they did not have a clinical waste collection contract in place and the waste disposal bin did not have working pedals which could affect how hygienically staff could dispose of clinical waste if required.

Staff did not always carry out daily safety checks of specialist equipment. There was paperwork for staff to evidence that they had visually checked machinery daily, however, this did not detail what should be checked and had only been completed on a weekly basis.

Assessing and responding to patient risk

Staff did not complete and update risk assessments for each woman and therefore could not remove or minimise risks. Staff did not know what to do to act quickly when there was an emergency.

The service did not provide clear guidance to sonographers if unexpected results were identified on the ultrasound scan, this led to inconsistent action in response to abnormalities seen on scans. A complaint from a woman using the service stated that they had not been told about an abnormality seen on their scan, their care record showed that no referral had been made in response to the finding. Staff told us this was because the abnormality was common and often harmless to women, and that they would only usually make referrals for abnormalities for the fetus, however there was no process in place to specify this. However, we reviewed three patient notes which showed staff had shared information to keep women safe when finding anomalies on scans and referred the concerns to the NHS or early pregnancy unit.

Staff did not assess and manage risks such as allergies, health conditions or concerns as this information was not collected before scans on either women's booking information or consent forms.

There was no process in place to identify potentially vulnerable women. Health risks were not assessed during the booking or consent process; therefore, staff had no way of identifying whether potentially vulnerable women were safe having not attended the service. The 'Did not attend' policy stated that women would be contacted following having not attended a scan, but as staff would not be able to identify any risk factors this meant appropriate referrals could not be made to external professionals if required.

Inspected but not rated

Diagnostic and screening services

The service did not have processes in place for staff to recognise and respond promptly to any sudden deterioration in a woman's health. However, we observed an ultrasound scan where the wellbeing of the patient was regularly checked, and all staff told us they were aware to call emergency services in the event of any deterioration.

Staff did not know about or have processes in place to identify or respond to any specific risk issues such as sepsis.

Staff did not always follow the timeframes set out within the rescan policy. We observed a reassurance scan in which the sonographer stated that the fetus was measuring at under seven weeks. This was not in line with policy which stated that if the pregnancy was under seven weeks, they would not be able to confirm this and a rescan would be offered.

However, staff shared key information from scans with other healthcare professionals to keep women safe when their care was handed over to others.

Sonography staff used a 'pause and check' checklist to ensure that the correct person was receiving the correct scan. We observed this in practice during an ultrasound scan.

Staff advised women about the importance of attending their NHS scans and appointments.

The service's website signposted women to legitimate sources of information about potential risks of the use of ultrasound scanning.

The service had a general, COVID-19 and fire risk assessments and a fire risk evacuation procedure and environmental risk assessment in place.

Staffing

The service did not always have staff with the right qualifications, skills, training and experience to keep women safe from avoidable harm and to provide the right care. Managers regularly reviewed and adjusted staffing levels and skill mix and gave bank staff an induction.

The provider did not ensure that recruitment procedures to employ staff kept people safe

from harm. Disclosure and Barring service check's (DBS), an official record

stating a person's criminal convictions, had been gained from employee's previous

roles instead of their current employment. The provider's policy stated that a DBS check needed to be obtained for staff but did not specify whether the provider should acquire their own check of the employee or how often this should be reviewed. For one member of staff employed directly by the service, managers could not provide evidence of a complete Disclosure and Barring service

check (DBS). We did not see evidence of references collected for sonography staff.

The service did not currently have an employed sonographer to conduct scans for women. The manager had accessed sonography staff from another baby scan clinic, however we did not see a service level agreement in place between the clinics to clarify which clinic was responsible for ensuring staff had the right qualifications, skills and training to conduct keepsake scans.

Inspected but not rated

Diagnostic and screening services

The provider did not ensure staff were carrying out their role correctly in line with the providers

registration. We observed sonography staff taking measurements during scans which the service could not evidence that the staff member had the qualifications, skills or competence or appropriate registration with a professional body in line with the provider's website and recruitment policy.

The manager could adjust the amount of sonography lists they delivered a week, and the days on which they were carried out, dependant on the availability of sonography staff.

The service had one vacancy for a full-time sonographer which they had recruited to.

Records

Staff kept detailed records of women's care and diagnostic procedures. Records were clear, up to date, stored securely and easily available to all staff providing care.

Patient notes were comprehensive, and staff could access them easily.

Records were stored securely; the service had locked storage and computer systems to ensure records were only accessed by staff.

When women were referred to an external service, the service produced an obstetric report to hand over to health care professionals, however, the service could not evidence that sonography staff were appropriately qualified and experienced to produce these reports accurately.

Incidents

The service did not always manage safety incidents well. Managers did not always recognise when to investigate incidents and therefore could not share lessons learned with the whole team. When things went wrong, staff apologised and gave women honest information and suitable support. Managers ensured that actions from safety alerts were implemented.

The service had not reported any incidents. Managers investigated complaints and involved women and their families in achieving a desired outcome. However, it was not always recognised when safety incidents had occurred. In an audit of complaints, the manager had come to a satisfactory outcome with the complainant but not recognised that the complaint highlighted that the sonographer had not informed them of an abnormality identified during their scan and therefore had not reported or investigated this incident.

Staff gave examples of incidents they would report and told us they would be comfortable to raise concerns and report incidents to the manager.

Staff told us they understood the duty of candour. They were open and transparent and gave women and families a full explanation if things went wrong.

Staff received feedback from complaints through supervisions and informal meetings.

There was evidence that changes had been made as a result of feedback, staff had completed an effective communication course in response to complaint findings.

Inspected but not rated

Diagnostic and screening services

Are Diagnostic and screening services well-led?

Inspected but not rated

Leadership

Leaders did not evidence that they had the skills and abilities to run the service. They did not always understand and manage the priorities and issues the service faced. They were visible and approachable in the service for women and staff.

The service was led by the registered manager; however, we saw no evidence that they had accessed any training in leadership.

The manager told us they were from a non-clinical background, and it was the responsibility of individual sonographers to keep up to date with best practice. The manager did not have oversight of sonographer's clinical supervision to ensure that this was the case.

The manager often depended on the head office of the franchise to support the service in maintaining staffing levels, safe recruitment and clinical supervision. Despite the service being a separate clinic, there was no service level agreements or other contractual arrangements in place to ensure staff had clear responsibilities and were held accountable for actions taken at other locations.

However, managers were visible within the clinic during opening hours.

Staff told us they felt supported by the registered manager to develop with their role. A staff member told us, "I am proud to build with the business."

Vision and Strategy

The service had a vision for what it wanted to achieve. Leaders and staff were not aware of the actions required and therefore it was difficult to monitor progress.

The vision for the service was to build a reputable brand that was recognised.

The service had a business plan that included 10 actions required to achieve the vision. However, this did not assign ownership or timeframes to actions to ensure these were completed and achievable.

Culture

Staff felt respected, supported and valued. They were focused on providing women with a positive experience of baby scanning. The service had an open culture where women, their families and staff could raise concerns without fear.

The manager promoted a positive working culture within the service that supported and valued staff.

Staff we met were friendly, welcoming, and confident. They spoke positively about their roles and demonstrated pride in their work.

The service encouraged women and staff to raise any issues. We saw examples of where concerns had been investigated with a view to making improvements.

Governance

Leaders did not operate effective governance processes, throughout the service and with partner organisations. Staff were not clear about their roles and accountabilities and did not have regular opportunities to meet, discuss and learn from the performance of the service.

The providers recruitment and selection policy did not ensure that staff were safely recruited for their role. The policy stated that DBS records must be obtained for all employee's but did not specify the level of DBS required for each role or time frames to be reviewed. All DBS certificates we saw were completed by previous employers and were up to three years old.

At the time of our inspection, the provider did not have a process in place to ensure staff were suitably qualified for their role. Sonography staff were not employed directly from the service but were temporarily shared from another registered provider until the service successfully recruited their own. The manager did not ensure that staff had all the appropriate documentation for their role, both members of sonography staff did not have application and employment history, and there was no evidence of one sonographer having the appropriate registration with a professional body. There was no service level agreement in place to outline the responsibilities of each provider in relation to sharing staff.

The service did not have a robust process for monitoring the quality and accuracy of scanning. The manager told us that another baby scan provider checked sonographer reports and images for the accuracy and quality of the scans, but we did not see any documentation to support this. The service had not conducted any clinical audits to ensure the information women received was accurate and recording was correct; the manager told us these should have been conducted on a quarterly basis.

The provider did not have a process in place to monitor quality assurance and drive improvement. The quality assurance policy did not require the manager or staff to conduct any audit process to monitor the quality of the service. Only one patient record audit had been completed, this was provided and dated after inspection.

The provider did not have effective auditing systems and processes in place to identify shortfalls found on inspection such as incomplete recruitment records, lack of risk assessments. Audits that were in place were not always comprehensive enough to identify areas of risk and drive improvement, for example, the manager had not recognised a patient safety incident within their audit of complaints.

However, the service had policies in place that were up to date, reviewed and referenced current guidelines.

Management of risk, issues and performance

Leaders and teams did not use systems to manage performance effectively. They did not identify and escalate relevant risks and issues and identified actions to reduce their impact. They had plans to cope with unexpected events.

The provider did not have a policy in place to identify or respond to specific risk issues such as sepsis.

The service did not have a process to monitor and respond to a deterioration in women's health during their appointment in clinic. Staff told us they would ring emergency services, however, there was no process to identify when staff were required to escalate any deterioration.

Inspected but not rated

Diagnostic and screening services

The service did not have a plan in place to cope with unexpected events. We requested to see the business continuity plan following inspection, but this was not provided. This meant we did not see evidence that the provider had plans in place to respond to unforeseen circumstances such as loss of power.

Before the inspection the service did not have a clear and effective process for identifying, recording and managing risk. A local risk register was implemented after the inspection, and risks had been identified with control measures to help reduce any impact to the service.

However, this did not include review dates or some of the risks identified during inspection, including; a lack of policies, risks associated with a service providing treatment as a standalone clinic, financial viability and acknowledgement of no full-time sonography staff substantively employed within the service. Risks were not discussed during team meetings.

Information Management

The service did not always collect reliable data and analyse it. Staff could not always find the data they needed, in easily accessible formats, to understand performance, make decisions and improvements. The information systems were not always integrated and secure. The manager was aware to submit data or notifications to external organisations as required.

The service did not always collect, analyse and use information well to support its activities. The manager was developing an audit programme, however as the service was in its first year of operations, many audits had not been conducted due to a lack of relevant data.

Information was not always accessible; the manager was unable to provide information such as maintenance testing during inspection as they had stored this at home. However, this was provided after the inspection.

Systems were not integrated and secure. The manager shared information with the 'Baby ultrasound clinic' franchise, such as scan images for quality assurance, and this was sent by unsecured email. There was also no service level agreement in place regarding information sharing, however, computers in the reception area and ultrasound scanning machine were password protected.

Information on the website was not clear as it stated that 'the professional scanning team are all fully qualified radiographers working within the NHS' however, one radiographer who worked at the clinic could not evidence their qualifications and did not work within the NHS. In addition, the website stated no more than three scans will be provided as per British medical ultrasound society guidelines. However, we did not see any guidance in relation to the number of scans performed.

The service had not had any safety incidents; however, the manager was aware of their statutory duty to make notifications to external organisations as required.

Engagement

Leaders and staff did not actively engage with women, equality groups and local organisations to plan and manage services. They collaborated with partner organisations to help improve services for women.

Managers did not actively engage with women to plan and manage services. Managers sought feedback from women's experiences through email and monitored external reviews however, they did not use this information to plan and manage services.

Inspected but not rated

Diagnostic and screening services

Staff told us managers were approachable, supportive, and used the phone, emails, and team meetings for engagement. They were involved in the day to day running of the service.

Managers told us they collaborated with another clinic to help improve sonography scans and reports through assurance audits, however they were unable to evidence documentation of these audits or demonstrate any learning or benefits implemented from it.

Learning, continuous improvement and innovation

All staff told us they were committed to continually learning and improving the service. The registered manager told us they encouraged innovation and feedback from staff and service users. However, they were unable to provide examples of service improvements.

This section is primarily information for the provider

Requirement notices

Action we have told the provider to take

The table below shows the legal requirements that were not being met. The provider must send CQC a report that says what action they are going to take to meet these requirements.

Regulated activity	Regulation
Diagnostic and screening procedures	Regulation 18 HSCA (RA) Regulations 2014 Staffing • The provider did not ensure staff received support and training as is necessary to enable them to carry out the duties they are employed to perform. **(Regulation 18(2)(a))**

This section is primarily information for the provider

Enforcement actions

Action we have told the provider to take

The table below shows the legal requirements that were not being met. The provider must send CQC a report that says what action they are going to take to meet these requirements.

Regulated activity	Regulation
Diagnostic and screening procedures	Regulation 17 HSCA (RA) Regulations 2014 Good governance • The service did not ensure that there was a system and process used to confirm that individuals, employed for the purposes of carrying on a regulated activity, satisfies the necessary requirements, and is monitored for completeness. **(Regulation 17(2)(a))** • The service did not have systems and processes in place to assess, monitor and improve the quality and safety of the service, for example, regular audits.**(Regulation 17(2)(a))** • The service did not ensure that when working with other organisations there were agreements in place to ensure staff had clear responsibilities and were held accountable for actions taken at other locations. **(Regulation 17(2)(a))** • The service did not ensure that when working with other organisations there were agreements in place to ensure the safe and secure sharing of information. **(Regulation 17(2)(a))** • The service did not ensure that it had an escalation process in place in the event of recognising abnormalities during ultrasound scanning. **(Regulation 17(2)(b))** • The service did not assess risks to women's health before delivering keepsake scans. **(Regulation 17(2)(b))** • The service did not have a process in place to ensure staff were adhering to rescanning timeframes outlined in provider policy. **(Regulation 17(2)(b))** • The provider did not ensure incidents that affect the health, safety and welfare of people using services are recognised and reviewed and thoroughly investigated by competent staff, and monitored to make sure that action is taken to remedy the situation, prevent further occurrences and make sure that improvements are made as a result. **(Regulation 17(2)(b))**

This section is primarily information for the provider

Enforcement actions

- The service did not ensure they had processes to assess, monitor and mitigate the risks relating to the health, safety and welfare of service users and others who may be at risk which arise from the carrying on of the regulated activity. **(Regulation 17(2)(b))**
- The service did not have a process in place to ensure that specialist machinery was frequently cleaned to prevent and control the spread of infections. **(Regulation 17(2)(b))**
- The service did not have a process in place to ensure that specialist machinery is frequently and robustly checked to ensure it is safe for use. **(Regulation 17(2)(b))**
- The provider must ensure they have evidence that staff meet the professional standards which are a condition of their ability to practise or a requirement of their role. **(Regulation 17(2)(c))**