Baby It's You Limited

Quality Report

Unit 3
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Date of inspection visit: 08 February 2019
Date of publication: 21/06/2019

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	Inadequate
Are services safe?	Inadequate
Are services effective?	Not sufficient evidence to rate
Are services caring?	Requires improvement
Are services responsive?	Requires improvement
Are services well-led?	Inadequate

Overall summary

Baby Its You Limited is operated by Baby Its You Limited. The service is a single speciality independent healthcare provider offering 3D, 4D and early pregnancy scans to self-funding or private people who use the services.

Baby Its You Limited is situated in a small business unit, along a busy central road within Doncaster. The unit is wheelchair accessible and has designated car parking at the front of the building. People who use the services enter directly into a large waiting area with a separate scanning room, customer toilet, small kitchen and second toilet area accessed through separate doors. The central reception has adequate seating and two reception desks.

Summary of findings

The studio provides a screening and ultrasound scan service for people who use the services aged 17 to 65 in relation to pregnancy (from seven through to 38 weeks gestation).

We inspected this service using our comprehensive inspection methodology. We carried out the short-announced inspection on 08 February 2019. We had to conduct a short-announced inspection because the service was only open if people who used the services required it.

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

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

Services we rate

We had not previously inspected this service.

This is the first time we have rated this service. We rated it as **Inadequate** overall because:

- Safety systems, processes and standard operating procedures were not fit for purpose.
- There was insufficient attention to safeguarding children and adults.
- Care premises were unclean.
- Staff did not assess, monitor or manage risks to people who used the services.
- Opportunities to prevent harm to individuals were missed.
- Individuals care, and treatment was not delivered in accordance with evidenced based practice or national guidance.
- People received care and treatment from staff that did not have the skills or knowledge to deliver effective care.
- Staff did not protect the privacy and dignity of people who used the service.
- Leaders did not have the necessary experience, knowledge capacity and integrity to lead effectively.
- Governance process were unclear and there was a lack of systematic performance management which included the failure to identify and manage risk.

Following this inspection, we undertook due process regarding the significant safety concerns and told the provider to suspend regulated activities at the location.

Services which have been suspended must be re-inspected before they can re-open. If insufficient improvements have been made such that there remains a rating of inadequate overall or for any key question or core service, we will take action in line with our enforcement procedures to begin the process of preventing the provider from operating the service. This will lead to cancelling their registration or to varying the terms of their registration within six months if they do not improve. The service will be kept under review and, if needed, could be escalated to urgent enforcement action. Where necessary another inspection will be conducted within a further six months, and if there is not enough improvement we will move to close the service by adopting our proposal to vary the provider's registration to remove this location or cancel the provider's registration.

I am placing the service into special measures.

Services placed in special measures will be inspected again within six months. If insufficient improvements have been made such that there remains a rating of inadequate overall or for any key question or core service, we will take action in line with our enforcement procedures to begin the process of preventing the provider from operating the service. This will lead to cancelling their registration or to varying the terms of their registration within six months if they do not improve. The service will be kept under review and, if needed, could be escalated to urgent enforcement action. Where necessary another inspection will be conducted within a further six months, and if there is

Summary of findings

not enough improvement we will move to close the service by adopting our proposal to vary the provider's registration to remove this location or cancel the provider's registration.'

In addition, we issued a warning notice in relation to Regulation 10, 12 and 17 and told the provider that it must take some actions to comply with the regulations. We also issued the provider with one requirement notice with 15 actions they must complete that affected Baby Its You Limited.

Following a further visit to the provider to check compliance, the suspension of the service was lifted.

Details are at the end of the report.

Ellen Armistead

Deputy Chief Inspector of Hospitals (North)

Summary of findings

Our judgements about each of the main services

Service	Rating	Summary of each main service
Diagnostic imaging	**Inadequate** 	The service provided at this location was diagnostic and screening procedures. We rated this core service as inadequate overall. There were insufficient systems to monitor safety, outcomes and experience for people who used the services. Appropriate, nationally referenced guidelines and policies were not developed by the provider. Opportunities to prevent harm to individuals was missed and staff did not maintain the privacy and dignity of people who used the services. Risk, governance and operational performance arrangements were not fit for purpose. Staff were not sufficiently skilled or qualified to deliver effective care and treatment to individuals using the service.

Summary of findings

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Inadequate

Baby It's You Limited

Services we looked at
Diagnostic imaging

Summary of this inspection

Background to Baby It's You Limited

Baby Its You Limited is operated by Baby Its You Limited. It is a single speciality independent healthcare provider, which opened in Doncaster in 2013. The service primarily serves the South Yorkshire; however, people who use the services can travel to the unit from all areas of the Country.

The service has had a registered manager in post since 2013. The service is registered for the following regulated activities:

- Diagnostic and screening procedures

We conducted a short-announced inspection of the service on the 08 February 2019.

Our inspection team

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

Information about Baby It's You Limited

The studio is registered to provide the following regulated activities:

- Diagnostic and screening procedures.

During the inspection, we inspected the 3D/4D, sexing and early pregnancy imaging services.

We spoke with four staff who were the sonographer who conducted the imaging, the managing director who was also the registered manager, one receptionist and the office manager. The registered manager was also the safeguarding lead.

We observed four people using services and their relatives and reviewed two records of people who used the services.

There were no special reviews or investigations of the service ongoing by the CQC at any time during the 12 months before this inspection.

Activity - November 2017 to October 2018 (reporting period)

In the reporting period there were:

- Four complaints, all of which were upheld

The service at the location employed one sonographer, an office manager and three reception/production technician staff.

Opening times at the location depended on demand.

The service outsourced a number of buildings and equipment maintenance services with third party providers.

Track record on safety:

- Zero people deaths or never events (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), or serious incidents.
- Zero 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 people who use the services (or other relevant persons) of certain 'notifiable safety incidents' and provide reasonable support to that person).
- Zero safeguarding referrals.

Summary of this inspection

- Zero incidences of healthcare acquired infections.
- Zero unplanned urgent transfers of a patient to another health care provider.
- The provider reported 10-15 cancelled appointments for a non-clinical reason within the reporting period December 2017 to November 2018.

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?

Are services safe?

Inadequate

We rated safe as inadequate because:

- The provider did not identify or provide mandatory training in key skills to staff.
- Staff did not understand how to protect people who use the services from abuse and children and adults were not sufficiently safeguarded.
- Procedures and policies were not in place to safely care for individuals appropriately. This included the failure to identify the care of the deteriorating patient.
- The provider did not ensure the premises were sufficiently clean or carry out any environmental audits to ensure infection prevention control measures were in place.
- Risk was not recognised or managed appropriately.
- Service user records which included care, treatment and financial information, was not stored confidentially.
- There was no incident reporting system in place. Staff did not recognise concerns, incidents or near misses.
- The provider did not ensure staff had completed necessary disclosure and barring checks.

Are services effective?

Not sufficient evidence to rate

We currently do not rate effective, however, we found:

- The provider did not develop policies or procedures to ensure care and treatment was delivered in line with national guidance and best practice.
- The provider did not monitor the effectiveness of care and treatment delivered or monitor outcomes to drive improvement.
- The service worked in isolation and did not interact with external professional bodies with the specialism.
- Staff did not understand how and when to assess whether a person had the capacity to make decisions about their care or understand their roles and responsibilities under the Mental Health Act 1983 and the Mental Capacity Act 2005.

Are services caring?

Requires improvement

We were unable to rate caring because:

- People were not valued as individuals or empowered as partners in their care.

Summary of this inspection

- Feedback from people who use the services was limited.
- Individual's privacy and dignity was not always protected.
- The provider had little appetite to seek the views of people who use the services.

However:
- Individuals we observed using the services appeared positive regarding their care and treatment.

Are services responsive?

Requires improvement

We rated responsive as requires improvement because:

- We saw appointments were cancelled or rearranged due to availability of a sonographer or mechanical or equipment failure, and we did not see an action plan in place to improve this.
- Staff did not receive training or guidance to ensure individuals with a specific need such as dementia or learning disability were sufficiently supported.
- We did not see evidence of translation services for individuals whom English was not their first language.
- The service did not have a robust system in place to collate, investigate and learn from complaints.

However:
- Individuals were able to book flexible appointments at a time that suited their needs.

Are services well-led?

Inadequate

We rated well-led as inadequate because:

- Leaders in the service did not have the right skills and abilities to effectively run the service.
- There was not an effective governance framework in place. The service did not review its practice in line with national clinical guidelines or review staff training or competencies.
- Policies and procedures were not in place for any aspect of clinical care and treatment delivered.
- Robust arrangements for identifying, recording and managing risks were not in place. For example, there was no incident reporting system in place.
- Staff were not recruited appropriately and staff records containing essential recruitment checks, training and professional registration was not in place.
- The provider did not complete any audits to monitor the effectiveness of the services provided.
- We did not see evidence of staff meetings or discussion to routinely update and share information.

Summary of this inspection

- The service had limited engagement with people who used the services and did not routinely look to seek feedback regarding the services provided.

Detailed findings from this inspection

Overview of ratings

Our ratings for this location are:

	Safe	Effective	Caring	Responsive	Well-led	Overall
Diagnostic imaging	Inadequate	Not rated	Requires improvement	Requires improvement	Inadequate	Inadequate
Overall	Inadequate	Not rated	Requires improvement	Requires improvement	Inadequate	Inadequate

Inadequate

Diagnostic imaging

Safe	Inadequate
Effective	Not sufficient evidence to rate
Caring	Requires improvement
Responsive	Requires improvement
Well-led	Inadequate

Are diagnostic imaging services safe?

Inadequate

We rated safe as **inadequate.**

Mandatory training

The provider did not have a mandatory training programme for staff. The registered manager told us that all training was delivered to staff when they were recruited but did not have a written record of the training completed.

Staff we spoke with during inspection told us that training had been provided and included bookings, appointment arrangements, security of the premises and administration.

The registered manager told us that all staff were supervised until they were deemed to be competent, but no record of this supervision was maintained.

No staff files were maintained, however we asked for copies of any training that had been provided to staff by the provider. We were not provided with any evidence of staff training delivered by the provider.

We saw the office manager had completed Adult Basic Life Support (BLS) training but this was completed during a previous employment in 2016. The office manager told us that this training was not relevant to their current role and had not received any further guidance or training by the provider.

We spoke with the sonographer on duty and asked if support was made available to enable completion of continuous professional development (CPD). We were told that no provision had been made by the provider but CPD was maintained through a different employment post that was currently held.

We saw a certificate which corroborated CPD but this was dated 2010. We did not see any other records to demonstrate current CPD.

On the follow up inspection to review the suspension and the actions taken by the provider to address immediate patient safety concerns, we saw evidence of training records for all staff.

Safeguarding

The provider did not have a safeguarding policy at the time of inspection.

The registered manager was the designated safeguarding lead for children and adults.

We reviewed safeguarding training and saw that the registered manager held level 1 safeguarding training for children and adults. This training was completed as part of external church work through the Diocese of Sheffield.

We asked the provider if any of the staff working at the clinic had completed appropriate safeguarding training. We were provided with a training certificate for one of the receptionists whom had also completed the same safeguarding course with the church.

None of the staff employed by the provider had completed safeguarding training relevant to their current role and therefore not in line with intercollegiate

guidance 'Safeguarding Children and Young People: roles and Competencies for Healthcare Staff' (March 2014) or intercollegiate guidance 'Adult Safeguarding: Roles and Competencies for Health Care Staff (August 2018).

Staff we spoke with did not understand how to protect patients from abuse or how agencies work together to protect individuals from harm.

Staff we spoke with had not made any safeguard referrals and did not know what process to follow if they needed to make a referral.

There was no written policy to support staff in reporting female genital mutilation (FGM), child sexual exploitation (CSE) or PREVENT which specifically covers the exploitation of vulnerable adults who may be drawn into terrorism. However, staff we spoke with could articulate what they would do if they came across a person with FGM and confirmed that the safeguarding training they had received covered FGM and PREVENT. None of the staff we spoke with understood FGM or PREVENT.

We did not see evidence of appropriate staff safeguarding training or safeguarding processes in place to enable staff to raise safeguarding alerts. Therefore, we were not assured the service protected individuals from harm.

On the follow up inspection to review the suspension and the actions taken by the provider to address immediate patient safety concerns, we saw evidence that all full time staff had started to complete appropriate safeguarding training or were registering to start the training. We saw evidence of a safeguarding policy and the registered manager described how safeguarding would be recorded; this was not in place at the time of the visit. The registered manager had initiated a relationship with the local safeguarding team and was more aware of the wider safeguarding community.

Cleanliness, infection control and hygiene

The provider did not have infection prevention and control policies or cleaning schedules.

The service did not always control infection risk well. Staff did not always keep themselves, equipment and the premises clean. For example, we saw the small kitchen area which was used to prepare drinks for service users was visibly dirty with a heavily soiled cleaning cloth hanging over the sink. We saw a seat was placed in the service user toilets which was covered with material. We saw this was also visibly dirty.

Staff used paper towel to cover the examination couch during a scanning procedure. However, we did not see staff clean the couch in between each person's scan.

Hand hygiene audits were not undertaken to measure compliance with the World Health Organisation's (WHO) '5 Moments for Hand Hygiene.' These guidelines are for all staff working in healthcare environments and define the key moments when staff should be performing hand hygiene to reduce risk of cross contamination between patients. We saw clinical staff did not adhere to bare below the elbow requirements or wash their hands prior to performing each scan.

Staff did not adhere to the standards of the DH Health Technical Memorandum 07-01 in relation to safe standards of waste disposal, including clinical and hazardous waste. For example, we did not see clinical waste segregated into secure and colour-coded bags.

The provider did not carry out any infection control audits.

The scanning room floor was covered in a washable surface, but we did not see any evidence of cleaning schedules.

There was no evidence the service undertook audits of staff adherence to personal protective equipment procedures, infection prevention and control procedures, or in relation to the completion of patient records. We were not therefore assured the service protected people from harm.

Environment and equipment

The premises were wheelchair accessible and had designated parking at the front of the building, which was free of charge. The building was managed by the building landlord and people who use the services were directed by clear signage to the front entrance which opened into a large waiting area.

The reception / waiting area had adequate seating and drinks were made available to individuals upon request.

We saw service user toilets and a separate staff kitchen with an additional toilet at the end of the kitchen.

Diagnostic imaging

The scanning room was accessed from the central waiting area. Two reception desks were situated in the reception area and were staffed by a receptionist who also acted as a production assistant.

The scanning room contained seating, the couch and the ultrasound system, together with a large TV for people who used the services to view the scan. All machine faults were recorded by the registered manager, and servicing was carried out under a service level agreement by the manufacturer.

We saw evidence of small electrical appliance testing equipment labels in the scanning room but saw no evidence of testing certificates or a testing/maintenance schedule.

Staff told us that they had adequate stock at the location, such as, antiseptic wipes and paper cleaning roll.

We saw some of this stock was stored in the kitchen area, upon shelving above the kitchen sink and on the floor in the toilet.

We saw these areas were not well maintained and items were not neatly organised or stored away appropriately. The kitchen bench was cluttered with an array of items, such as first aid kits, empty CD boxes, crayons, food items and service user documents.

A member of staff told us that occasionally service users would use this area if they required the additional toilet facilities.

There was no evidence the service adhered to infection prevention control measures to promote a safe clean environment and therefore we were not assured that this environment protected people from harm.

Assessing and responding to patient risk

The provider did not have a risk assessment policy or produce any guidance for staff around potential risks.

We saw a staff manual had been developed by the provider but contained only one sentence in relation to clinical risk. This related to people who used services attending for a scan but were bleeding. The advice within the manual was factually incorrect as it stated CQC stated “providers are not allowed to see service users whom are bleeding”.

We spoke with the office manager who told us that all people who used services were asked to complete a questionnaire when booking a scan. We asked what concerns would be escalated following completion of the question, but we were not assured that clerical staff had sufficient skills or knowledge to appropriately recognise clinical concerns. Staff we spoke with were not able to define risk within the service and told us they would highlight any concerns to the registered manager.

The provider did not produce any guidance in relation to best clinical practice or refer to any service specific national guidelines.

We asked clinical staff what arrangements were in place to escalate abnormal scan results or support expectant mothers for whom a fetal heart beat was not detected. We were told that scan results would be shared with the relevant G.P or host midwifery unit but this practice came from external professional experience rather than any provider guidance.

The registered manager told us he was not aware of any risks within the service.

We saw within the staff manual that guidance in unforeseen circumstances should be referred to the medical director. The provider did not employ a medical director.

We did not see any evidence of robust risk identification, escalation or management processes. Risks associated with treatment and care were not considered, for example transvaginal scans. Therefore, we were not assured that the provider protected people from harm.

None of the staff employed had completed basic life support training which was specific to their role. The registered manager told us they had completed first aid training. We reviewed the certificate, but it was a course checklist which was not dated.

All staff told us they would ring immediately for an ambulance should a person feel unwell.

We did not see evidence documenting training or competency to carry out 3D and 4D imaging. We saw the sonographer carry out this scan during the inspection but later told us they were not trained to do so.

Diagnostic imaging

All scan reports were provided to people who used the services immediately following the scan. People who used the services were asked to hand this copy to their own GP's.

The service reported zero unplanned urgent transfers of a person to another health care provider and zero cancelled appointments for a non-clinical reason.

The registered manager told us they ensured there was always at least two staff available at the clinic which eliminated the risk of lone working.

We were not assured that staff had the sufficient knowledge or had been provided with the appropriate guidance to identify and escalate risk or concerns appropriately and therefore we are not assured that the service protected people from harm.

On the follow up inspection to review the suspension and the actions taken by the provider to address immediate patient safety concerns, we saw evidence of the qualifications for the clinical staff member which included internal (transvaginal) scans and 3D/4D scanning. Staff working at the service who conducted clinical work had appropriate enhanced disclosure and barring checks and we saw evidence of a safeguarding policy. Staff were in the process of registering for relevant safeguarding training and the registered manager had initiated a relationship with the local safeguarding team and the wider safeguarding community.

Staffing

The service staffed the location with one full time sonographer, and one full time office manager. Other staff including sonographers and receptionists were employed on an 'as needed' basis in line with service user demand with a qualified and accredited studio staff member. Both the registered manager and office manager also acted as production technicians when required.

The service also employed one part time receptionist and two part time production technicians, one full time radiographer and had contact information for other freelance sonographers and staff who were used on an ad hoc basis to cover the service but were not employed on a regular contract.

In the period October 2017 to November 2018, there had been no vacancies for directly employed staff and the service did not use bank or agency staff. Also, there had been no sickness in this period.

We did not see evidence of registration for the other sonographers working at the service.

The registered manager did not maintain National Midwifery Council (NMC) registration details for the nurses and midwives contracted or used on a freelance basis. However, electronic checks carried out on site confirmed that two of the sonographers were currently registered.

Only one of the six staff employed by the provider had completed a role specific enhanced disclosure and barring check. This also included the registered manager. We saw enhanced disclosure and barring checks had previously been completed through external organisations for the registered manager, the office manager and one of the receptionists but these were not transferable to this service.

We did not see evidence of any disclosure and barring checks in place for the sonographer on duty, or the additional staff whom are used on an as and when required basis for this service.

We did not see systems in place to ensure all staff working at the service were appropriately supported with the necessary training and skills or had received the appropriate safe staffing checks and therefore we were not assured that the provider protected people from harm.

On the follow up inspection in relation to the suspension of the service, we saw evidence of enhanced disclosure and barring checks for the four permanent staff who worked at the service; this included the registered manager.In addition, we saw evidence that staff training systems had been implemented; however, as they were new, we did not see they were embedded in the service.

Records

All people who used the services received two copies of their report after their scan.

No NHS records were held by the provider and only basic terms and conditions and the initial booking forms were held on the person's record.

Inadequate

Diagnostic imaging

We saw several box files of patient records were stored above the staff kitchen sink area and in the additional toilet. We reviewed five of these box files and saw that they contained personal patient information. We brought this to the attention of the registered manager immediately and asked that the information be stored securely and appropriately. We saw this was done during the inspection.

Scanning images were sent directly from the scanning machine to a shared file on the reception computer. We saw the image files were not password protected, although the computer itself was.

The provider told us that scanning images were sent through social media sites if requested. We were not assured that this was a protected method of sharing images.

Incidents

The provider did not have an incident identification, investigation or management policies or produce any guidance for staff in relation to incidents.

Staff did not receive any training from the provider in relation to incidents.

We saw the service completed a premises accident book.

In the 12 months before the inspection the location did not report any patient deaths or never events (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 person harm or death but neither need have happened for an incident to be a never event), or serious incidents.

In the same period there had been zero 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 people who use the services (or other relevant persons) of certain 'notifiable safety incidents' and provide reasonable support to that person).

Staff told us they would determine from their own knowledge what would be deemed as an incident and discuss it with the registered manager. However, as there was no evidence in relation to incident identification and management, we were not assured that the service protected people from harm.

Are diagnostic imaging services effective?

Not sufficient evidence to rate

The effective domain was not rated.

Evidence-based care and treatment

The provider had developed a staff manual as a tool to support staff with the day to day running of the service. We reviewed the manual and saw that it included guidance of the practical arrangements such as appointment bookings, payments and refunds.

The manual did not include clinical guidance. For example, protocols and pathways to support safe care and treatment of people who used the services.

The provider did have policies, procedures and guidance in relation to diagnostic procedures. For example, standard operating procedures based on national best practice and guidelines for the safe use of diagnostic ultrasound equipment from the British Medical Ultrasound Society (BMUS).

The unit did not participate in or carry out any audits. For example, infection control, booking forms, image quality, principles and safety problems of diagnostic ultrasound guidelines (ALARA).

Staff told us that they discussed issues with the director, but we did not see evidence of any staff meetings.

The service worked in isolation. We did not see evidence of external liaison. For example, staff attending national conferences or development days relevant to the specialism.

On the follow up inspection to review the suspension and the actions taken by the provider to address immediate patient safety concerns , we saw evidence of a policy which included clinical guidance.

Nutrition and hydration

There were no formal nutrition services for people who use the services that attended the service. However, staff had access to a selection of refreshments (tea, coffee and water) which they provided to people who use the services when requested.

Patient outcomes

Patient outcomes were not monitored by the provider.

Each person seen at the studio had an allocated time slot to ensure sufficient time for each scan. For example, a wellbeing and gender scan was allocated 15 minutes but the appointment time for the people who used the services was 10 minutes. This allowed sufficient time for the sonographer to summarise and assess the outcome of each scan.

Competent staff

The director did not maintain staff files, therefore staff training was not recorded or monitored.

The provider did not maintain records of appropriate staff recruitment. For example, completed application form to work at the service, a history of employment, successful interview records, supply professional references, or carry out enhanced disclosure and barring checks, which were appropriate to the current staff job role.

Sonographers as healthcare professionals should be registered with the Health and Care Professions Council (HCPC) and have met the standards to ensure delivery of safe and effective services to people who use the services. The HCPC is a regulator, set up to protect the public. They keep a register of health and care professionals who meet HCPC standards for their training, professional skills, behaviour and health.

We saw the provider employed a full time sonographer whom was an HCPC registered radiographer and met the standards to ensure delivery of safe and effective services to people who used the services.

However, we did not see evidence of registration with the HCPC for freelance sonographers.

On-going staff competence was not managed through quality assurance review processes or audits.

We asked the sonographer on duty if they had been supported with continued professional development (CPD) to meet their professional body requirements by the provider, but they had not.

The director delivered all staff training and in addition, provided people who used the services with an introductory talk about the scan they would receive upon arrival. We observed these introductory talks and heard that they were not always appropriate to the needs of the individual. For example, service users were told that the service was an 'unofficial pressure release' for the local hospital.

In addition, the director did not hold any clinical experience or qualification and therefore we were not assured that they were appropriate to provide these services.

On the follow up inspection to review the suspension and the actions taken by the provider to address immediate patient safety concerns, we saw evidence of enhanced disclosure and barring checks for appropriate staff were in place and staff files had been created. The registered manager described recruitment checks that would take place for staff recruited going forwards, in addition we saw evidence of a recruitment process and procedure following the visit. We also saw evidence of staff training records held in the staff files.

Multidisciplinary working

We did not see evidence of any multi-disciplinary working. The director told us that they spoke to staff working in senior positions relating to healthcare, but this interaction did not appear to have any positive impact or benefit to the running of the service.

We observed staff interaction during inspection and saw that staff communicated effectively to ensure smooth running of people who used the services appointments.

Seven-day services

At the location services were supplied depending on demand which meant services at the location were not necessarily open seven days a week.

The director told us that individuals received a 'better service' Monday to Friday as there were less people booked in.

Consent and Mental Capacity Act

Inadequate

Diagnostic imaging

The provider didn't have any policies or guidance in relation to mental capacity and consent. The provider told us that only adults were seen at the clinic but occasionally 17 year olds might be accepted, however they were discouraged from using the services.

We did not see evidence of training in relation to mental capacity and consent and we were not assured that people who use the services were offered a fair and consistent level of service following the provider's informal selection process.

We saw that the service obtained written consent from the people who used the services within the initial individual scanning questionnaire. However, none of the staff had received training in relation to consent and we were not assured that staff were competent to support people to make an informed decision regarding their care and treatment.

Are diagnostic imaging services caring?

Requires improvement

We rated caring as **requires improvement**.

Compassionate care

Staff did not always treat individuals with dignity, kindness, compassion, courtesy and respect. We observed staff failing to ensure the privacy and dignity of individuals attending for scans.

We saw an example where privacy and dignity of a person using the service was not maintained. The modesty curtains in the scanning room did not close properly and were held shut by the sonographer while people receiving an intimate scan prepared themselves. The curtains were opened so the viewing screen could be seen during the scan. There was no lock on the door to the scanning room or indication an intimate scan was taking place which meant anyone could access the room during the scan.

The provider sought limited feedback from people who use the services. We saw comments could be made through the provider's social media website, but we did not see any proactive tools to engage with service users in order to gain feedback.

We were unable to review the most recent service user feedback as comments were not collated by the provider and social media feedback whilst positive, was limited.

During the inspection we observed staff interaction with people who used the service. We saw staff introduced themselves to people who used the services and explained the procedures and scanning practice.

We saw people who used the services appeared happy with the information and treatment provided, but there was no opportunity to speak with individuals privately regarding their care and treatment.

Following inspection, we spoke with an additional three people who use the services, who provided extremely positive feedback. One person told us 'This is the only baby scan provider that I am at ease with. They really respected my medical expertise and totally tailored the service to my needs. The staff are exceptional, and I would not hesitate to recommend them'.

Emotional support

Staff did not understand the potential impact a person's care, treatment or condition had on their wellbeing and on their relatives, both emotionally and socially. The registered manager described the style of communication used when supporting individuals with abnormal scan results or undetectable fetal heartbeats. The term 'lighten up' was used after scans were completed.

The sonographers we spoke with told us that they had several years' experience carrying out early scans and supporting parents receiving such news and felt able to support individuals in these circumstances.

None of the staff at the unit had undergone any additional training, such as breaking bad news, to appropriately support individuals.

Staff told us that scan buddies were provided at all appointments and we were able to corroborate this during inspection. These buddies' provided assistance to both the person using the service and sonographer in the scanning room.

The registered manager told us that parents and carers of small children were able to stay in the scanning room during procedures.

Inadequate

Diagnostic imaging

Understanding and involvement of people who use the services and those close to them

The sonographer on duty at the time of inspection told us that if the gender could not be clearly identified on the scan then the service user would be invited back for a complimentary scan.

Are diagnostic imaging services responsive?

Requires improvement

We rated responsive as **requires improvement.**

Service delivery to meet the needs of local people

The service did not have links with the wider service specific community such as external ultrasound departments in the wider NHS and therefore did not refer to any other organisations.

The business unit was situated near established routes, with a bus stop and a train station a short distance away. Patients were also able to use free and accessible car parking. We saw complimentary parking permits were given to users of the service.

The service offered a range of appointment times and days to meet the needs of the patients who used the service. However, we saw a number of appointments were cancelled due to the unavailability of the sonographer. We asked the provider what action had been taken to improve the number of cancellations and, although we requested further information, we did not see evidence of an action plan to improve this.

Appointments for scans were booked using either the provider's website or individuals could ring the receptionist who would book them into an appointment which best suited their requirements.

There was sufficient space in the reception and scanning room for individuals to accompany a patient, for example, carers, family, partners as well as patients.

Meeting people's individual needs

Reasonable adjustments were made so disabled people who use the services could access and use services on an equal basis to others.

Staff told us they rarely had patients attend their clinics for a scan that had complex needs, for example, learning disability or dementia. The provider did not offer any guidance or training for staff in relation to appropriate support for individuals with a specific need.

Staff told us that there was no provision of information in any language other than English and we did not see evidence of any interpreters used or availability of interpreting services.

People who used services we spoke with told us they felt they had sufficient time for their scans and did not feel rushed in any way.

We saw the provider had installed a large ultrasound screen which was placed at the foot of the bed making viewing images much easier and more comfortable.

Access and flow

People who used the services could book an appointment at a time to suit them and appointments took place according to demand, with staffing organised accordingly.

The service did not have a waiting list.

Appointment times were planned and timed to allow sufficient time for the sonographer to record and review scanning reports.

However, we saw fifteen cancelled appointments; 10 cancellations were due to availability of the sonographer and five cancellations were due to mechanical or equipment failure.

All people who use the services we spoke to were positive about the availability of scans and they told us that they had received appointments in a timely fashion that they were happy with.

Learning from complaints and concerns

The provider did not have a robust system to enable individuals to manage and investigate complaints and compliments. There was no clear guidance for people who use the services to raise a complaint or clarify how complaints would be reviewed and resolved.

Staff told us a note book was situated in the reception area and individuals were invited to write feedback in the

book. In addition, people who use the services could also provide feedback through the provider's website although there was no information specific to complaints on the provider's page.

The provider reported 60 compliments and 4 complaints between December 2017 and November 2018. We asked the provider to share further information with us, but they were unable to provide it.

Are diagnostic imaging services well-led?

Inadequate

We rated well led as **inadequate.**

Leadership

The director of the organisation was also the registered manager, trainer for all staff employed and lead for governance and quality.

The director was supported by one full time radiographer and one full time administrator.

Staff told us that they would refer to the director for all queries and stated that the director could be contacted whenever they required assistance.

In addition, staff told us they had been supported with 'on the job' training by the director and described the computer bookings system and arrangements for appointments and payments.

We did not see evidence of any staff meetings, but staff told us they regularly discussed operational issues.

The director asked inspectors where to find information regarding regulations and responsibilities of the registered manager and therefore we were not assured that the director had the skills, knowledge, experience, and integrity to lead the organisation.

Vision and strategy

The provider did not have a written vision and strategy but told us that it was hoped a second location could be opened in the future, which offered the same services as Baby Its You, Doncaster.

Due to the small nature of the service, there was no overarching plan for achieving priorities in the service.

Culture

The director told us that they lead by example, had worked in the field of medical imaging for 25 years and knew what was expected of an imaging service.

Staff spoke with inspectors openly and were able to define their roles within the organisation. The director often worked in supportive roles such as receptionist or production assistant and staff told us this was helpful.

We observed staff working together in the unit to ensure individuals appointments ran smoothly.

The provider did not have policies in relation to equality and diversity, although staff told us that all patients were able to use the services.

The provider did not have a duty of candour policy. We asked the provider to share further information with us, but they were unable to provide it.

Governance

There was a lack of effective governance framework to support the delivery of quality patient care. For example, the service failed to develop policies and procedures for any of the clinical roles that staff undertook. This included care of the deteriorating patient.

There were no policies in place to ensure clinical practice was in line with national guidance or best practice.

The provider did not develop any infection control policies or procedures to sufficiently monitor or maintain the cleanliness of the environment.

The provider did not develop policies and procedures to protect service user's privacy and dignity.

The provider did not develop policies and procedures in relation to mental capacity and consent to enable service users to make an informed decision regarding their care and treatment.

The provider did not identify mandatory training for any of the staff working within the organisation or ensure that records were sufficiently maintained for all staff working for the service.

There was no evidence of safeguarding training in line with the intercollegiate guidelines; this included the registered manager.

Inadequate

Diagnostic imaging

The provider did not carry out any audits to review current practice and drive improvement.

On the follow up inspection to review the suspension and the actions taken by the provider to address immediate patient safety concerns, we saw evidence of clinical guidelines for deteriorating patients in a policy which had been developed with guidance from a local NHS hospital.In addition, we also saw evidence that all full-time staff had started to complete appropriate safeguarding training or were registering to start the training. This was ongoing and will be monitored through our provider engagement process.

Managing risks, issues and performance

The provider did not have a risk register for the service and had not completed risk assessments for any aspect of the service or the working environment.

The service did not have a business continuity plan covering failure of utilities and such, like electricity or water.

The provider did not have formal recruitment processes for all staff, which included checking references, curriculum vitaes, or photographic identification. In addition, there was no evidence of disclosure and barring checks for four of the five staff we reviewed.

However, the provider ensured staff did not work alone by rostering two staff in the unit at all times.

On the follow up inspection to review the suspension and the actions taken by the provider to address immediate patient safety concerns, we saw evidence of enhanced disclosure and barring checks for appropriate staff were in place and staff files had been created. The registered manager described recruitment checks that would take place for staff recruited going forward, and we saw evidence of a recruitment process and procedure following the visit.

Managing information

We saw the provider did not take appropriate measures to safely store confidential service user records. The provider did not have a data management policy.

Staff had access to the provider's policies and resource material through the electronic computer system and office files.

The service was paper light and mainly used an electronic database to create and share service user information. Where paper was used, the completed paper form would be scanned onto the persons electronic record.

The provider told us that CD and DVD scanning image files had been now replaced with USB memory sticks. We saw that these sticks were stored in a lockable drawer, but we were not assured that the memory sticks were encrypted.

Engagement

The provider had limited appetite to seek service user feedback. The provider did not request service user experience surveys following scans.

However, people who used the services were engaged through the service's website and social media accounts, which promoted its services. The portals enabled people who used the services to compliment or complain about the services.

Learning, continuous improvement and innovation

We saw the provider maintained an innovation and improvement log following changes to operational practice following feedback from people who used the services. These included changes to services offered such as the introduction of growth measurements and presentation scans

The provider told us they had made a number of changes to the services, following feedback from people who use the services. These included the addition of a privacy curtain in the scanning room and introduction of memory sticks.

Outstanding practice and areas for improvement

Outstanding practice

We did not find any outstanding practice during this inspection.

Areas for improvement

Action the provider MUST take to improve

- The provider must ensure safeguarding processes are developed to ensure all staff fully understand how to report, investigate and learn from safeguarding alerts. In addition, all staff must receive training in line with Intercollegiate guidance (2018). Policy information must include FGM and PREVENT.
- The provider must develop policies and guidance in relation to all aspects of clinical care and treatment provided, which includes pathways for escalation, care of the deteriorating patient and referral of abnormal scan results.
- The provider must develop robust incident management processes, to ensure all incidents are reported, investigated and lessons learnt following incidents are shared.
- The provider must review and develop specific policy guidance in relation to mental capacity and consent and ensure staff have the necessary training and understanding in order to support service users to make an informed decision regarding their care and treatment.
- The provider must ensure that risks to patients are identified, assessed and monitored consistently and that action plans in assessments and care plans are updated and contain enough detail to enable staff to reduce those risks effectively. This includes environmental risk.
- The provider must ensure infection control measures are implemented and premises are sufficiently clean to deliver services.
- The provider must ensure the privacy and dignity of individuals is protected at all times during the delivery of care and treatment.
- The provider must ensure all staff have the necessary skills and training to enable them to be competent in their role.
- The provider must ensure all staff receive an appraisal every year.
- The provider must ensure staff are supported to maintain continuous professional development in line with professional registration requirements.
- The provider must ensure robust arrangements are in place, so that individuals understand how to make a complaint and staff investigate and learn following complaints.
- The provider must improve governance processes to drive improvement. This includes the implementation of clinical and environmental auditing and develop all policies to ensure staff provide care and treatment in line with national guidance and best practice.
- The provider must ensure all staff providing direct unsupervised care or treatment have completed enhanced disclosure and barring checks.
- The provider must ensure patients from different religious or cultural backgrounds have all their needs met and provide translation services when needed.
- The provider must maintain records for all staff employed which includes recruitment and vetting checks, training, professional registration, CPD and appraisal.

Action the provider SHOULD take to improve

- The provider should develop external relationships to strengthen professional understanding and share best practice within the service.

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 10 HSCA (RA) Regulations 2014 Dignity and respect **Regulation 10 HSCA 2008 (RA) Regulations 2014 Dignity and respect** **Regulation 10 (1) (2) (a) (b) (c)**

Regulated activity	Regulation
Diagnostic and screening procedures	Regulation 12 HSCA (RA) Regulations 2014 Safe care and treatment **Regulation 12 HSCA 2008 (RA) Regulations 2014 Safe care and treatment** **(1) (2) (a) (b) (c)**

Regulated activity	Regulation
Diagnostic and screening procedures	Regulation 17 HSCA (RA) Regulations 2014 Good governance **Regulation 17 HSCA 2008 (RA) Regulations 2014 Good governance** **(1) (2) (a) (b) (c) (i) (ii) (e) (f) (a) (e)**