Ultrasound Baby Face Ltd

Ultrasound Baby Face

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

Summary of findings

Overall summary

We carried out this unannounced focused inspection on 15th May 2021 because we had some concerns about the safety, quality, and leadership of the services. We did not inspect all key questions as defined within our methodology but focused on those areas highlighted in the warning notice issued by us on 8 October 2020.The inspection on 15 May 2021 was the first opportunity to follow up on the warning notice as the ongoing pandemic meant the service had been closed.

Focused inspections can result in an updated rating for any key questions that are inspected if we have inspected the key question in full across the service and/or we have identified a breach of regulation and issued a requirement notice, or taken action under our enforcement powers. In these cases, the ratings will be limited to requires improvement or inadequate.

Following the inspection, we issued a warning notice to the provider as we found significant improvement was required to improve governance systems and management and oversight of risks. The warning notice has given the provider 1 month to act on the significant improvements we identified.

This service has not previously been rated and as we only inspected parts of the key questions ratings only applied to the well-led question, which we have rated as inadequate. Please refer to the 'areas of improvement' section for more details.

Following a review of information supplied under section 64 of our powers and in response to the warning notice on 8 October 2020 and subsequent inspection on 15 May 2021, we have continued to monitor the provider's compliance and assess whether the provider had made improvements to comply with the relevant regulations.

Following the unannounced inspection, we found the service had made some improvements in relation to the concerns set out in the warning notice. Specifically;

- The service had an up to date safeguarding policy for children which set out the referral process for concerns, and who to contact. We also saw a referral process for women had been developed if a concern was noted during the ultrasound wellbeing check.
- The service had carried out a risk assessment for black and minority ethnic (BME) staff, and there were initial COVID-19 risk assessments for all patients and visitors including doorstep temperature checks prior to entering the clinic.
- Consent forms for patients over 18 years of age had been introduced to capture patient information, including confirmation of 12-week scan on NHS pathway and details of the patient's GP or Midwife in case of the need for a referral following the scan.
- Ultrasound equipment and the scan room were cleaned in-between all patients using appropriate anti-microbial wipes and checklists had been developed to monitor compliance with cleaning.

1.

However;

- The service did not have an up to date Statement of Purpose (SOP). The SOP showed the service still offered transvaginal scans as part of its early pregnancy scan package. The patient pathway document still referenced diagnostic examinations and non-obstetric scans.

Summary of findings

- There was also no business continuity plan or a record of pre employment checks the service would undertake for future staff if the current sonographer or any other staff member was off work. The service also did not have an incident reporting system or any other system to record any adverse incidents or near misses.
- The new safeguarding and abnormality referral processes were untested as they had been written as a response to the warning notice. The adult safeguarding policy which was submitted was incomplete, and the child safeguarding policy referenced out of date guidance and referred to staff and policies the service did not have.
- Consent forms labelled for use for anyone under 18 years of age stated they needed to be countersigned by a parent or guardian which. contradicted the consent policy.
- There was no evidence of any data to support the newly developed infection prevention and control checklist or hand hygiene audit checklist as they had not yet been implemented.
- There was no evidence or workplace risk assessments about lone working or manual handling in relation to use of the scan equipment.
- There was no established job specific training matrix for all staff. The service did not supply complete training data for any staff other than the sonographer. There was also no evidence of staff undertaking any basic life support training and there was no deteriorating patient policy.
- Scan quality was not monitored and there were no audits or a system for peer review. There was no evidence the service gave or signposted women to information around repeat scans and associated risks. Images which were stored on the ultrasound machine were not password protected.
- There was not an up to date organisational structure chart to reflect the number of staff working in the service.

Summary of findings

Our judgements about each of the main services

Service	Rating	Summary of each main service
Diagnostic imaging	Inspected but not rated	

Summary of findings

Contents

Summary of this inspection

Background to Ultrasound Baby Face

The service provides 2D, 3D and 4D ultrasound scans for non-diagnostic purposes and can project images into augmented reality (a type of virtual reality) to facilitate a bonding experience. The service sees women over 13 weeks in gestation following their 12-week NHS dating scan.

The service is registered to see patients from 13-18 years and 18-65 years

The service re-opened on 15 May 2021 following a period of dormancy due to the ongoing Covid-19 pandemic.

The service is registered to provide the following regulated activities:

- Diagnostic and screening procedures

The service has a registered manager, who has been in post since December 2014 when the service initially registered. The service had two employees including the registered manager. We have not previously inspected this service.

Prior to our unannounced inspection on 15 May 2021, we issued the service with a section 29 Warning Notice for non-compliance with Regulation 12 (1), safe care and treatment, of The Health and Social Care Act 2008 (Regulated Activities) Regulations 2014 and Regulation 17, (1) Good Governance, of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014

We issued this warning notice because we were concerned about to following;

Regulation 17, (1) Good Governance:

Risks to infections had not been assessed and actions taken to ensure these were managed in line with best practice guidance.

Policies were not reviewed to indicate essential training required for staff to perform their role.

The information submitted around consent lacked clarity on the process of obtaining informed consent from service users including those under 18.

The organisational structure chart submitted was not in line with previous reports of staffing levels.

There was no evidence there were systems to assess, monitor and improve quality and safety of the services provided and audits of scan quality had not been undertaken.

There was no business continuity plan and no evidence that the governance arrangements ensured a sustainable and responsive service.

Regulation 12, (1) Safe care and treatment:

Summary of this inspection

Consent documentation submitted referenced trainee doctors and treatment options such as medical treatment, immunisation, investigation or operation, which was not in line with the regulated activity the service was registered for.

There was no evidence that information about the limitations and potential risk of ultrasound scans was readily available to service users.

No evidence was submitted of staff completing the applicable safeguarding training. The 'Adults at Risk Policy' provided was not specific to the service and the 'Safeguarding Children' policy was incomplete.

Disclosure and Barring Service (DBS) application for the registered manager was in progress but there was no evidence to confirmed that staff members had a DBS check undertaken.

Training records and continuing professional development (CPD) for the registered manager was not submitted and a training policy was not provided.

There was no breakdown of training required per employee role, although there were listed six mandatory courses. There was no evidence that all staff had received the required training to enable them to fulfil their roles.

The patient pathway document suggested diagnostic procedures (such as thyroid and testicular ultrasound scans) were undertaken, which was not in line with information previously supplied during engagement.

The legionella policy and risk assessment were incomplete, so we were not assured that the risk of legionella was adequately managed.

There was no evidence that staff had completed infection prevention and control (IPC) training, or that there was an IPC policy for the service.

No risk assessments for BME had been undertaken and the registered manager did not how to differentiate between the needs of BME non-BME staff.

There was no COVID-19 risk assessment and the service had not been able to access personal protective equipment (PPE) and was still attempting to source PPE.

Following a review of information supplied under section 64 of our powers and in response to the inspection, we have continued to monitor the provider's compliance and this inspection was undertaken to review whether the provider had made improvements to comply with the relevant regulations.

How we carried out this inspection

During the inspection, we visited the registered location in the Galleries shopping centre in Bristol.

During our visit we spoke with the registered manager and the sonographer.

The inspection team consisted of one inspector and one inspection manager.

Summary of this inspection

As this was a focused inspection around aspects of the warning notice, we did not speak with people who use the service for their views.

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.

Outstanding practice

N/A

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:

We told the service that it must take action to bring services into line with legal requirements. This action related to one service.

- Update its statement of purpose to ensure it is relevant and accurate to the type of service provided. This includes the circumstances under which it scans patients over 16 years of age but under 18 years of age and references to diagnostic scans are removed. Regulation 17 (1) Good Governance.
- Define the consent process for 16- and 17-year olds to reflect its own policy and current legislation. Regulation 17 (1) Good Governance.
- Make sure all policies are service specific and reflect services provided, staff employed and reference the most up to date guidance. Regulation 17 (1) Good Governance.
- Develop a business continuity plan to include contingencies if the sonographer or any other member of staff is off work or unavailable. Regulation 17 (1) Good Governance.
- Ensure pre-employment checks are carried out in line with regulation and be able to demonstrate this has been done for all members of staff working in the clinic. Regulation 17 (1) Good Governance.
- Introduce basic life support training and establish a deteriorating patient policy should a patient become ill, whilst on the premises. Ensure all staff have received training identified as mandatory by the service. This must include training so that staff can respond in an emergency. Regulation 17 (1) Good Governance.
- Give patients information about any associated risks of having multiple ultrasounds, based on best practice guidance and advice from recognised professional bodies such as the British Medical Ultrasound Society. Regulation 17 (1) Good Governance.

Summary of this inspection

- Protect patient data stored on the ultrasound machine by using a password to gain access. Regulation 17 (1) Good Governance.

- Develop a way to record any adverse incidents so the service can investigate and learn from them. Regulation 17 (1) Good Governance.

1.

Action the service SHOULD take to improve:

- Audit and evaluate safeguarding and abnormality referral processes once they have been embedded into everyday practice.

- Collect and act upon data collected as a result of using the newly developed infection prevention and control checklist and hand hygiene audit checklist.

- Undertake all relevant workplace risk assessments for all staff particularly around lone working and manual handling in relation to use of the scan equipment.

- Develop a specific established training matrix for each member of staff and make sure up to date evidence is captured to show compliance with this.

- Establish a system of peer review to look at scan quality from a technical standpoint.

- Make sure organisational charts reflect the current staffing establishment.
- Consider monitoring rescan rates for patients.

Our findings

Overview of ratings

Our ratings for this location are:

	Safe	Effective	Caring	Responsive	Well-led	Overall
Diagnostic imaging	Inspected but not rated	Inspected but not rated	Not inspected	Not inspected	Inadequate	Inspected but not rated
Overall	Inspected but not rated	Inspected but not rated	Not inspected	Not inspected	Inadequate	Inspected but not rated

Inspected but not rated

Diagnostic imaging

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

Are Diagnostic imaging safe?

Inspected but not rated

We did not inspect this key question but focused on those areas highlighted in the warning notice as requiring significant improvement.

The rating was not assessed as part of this inspection.

Mandatory training

The service did not provide mandatory training in key skills to all staff or ensure everyone completed it.

Safety and safeguarding systems, processes and practices were not consistently developed, implemented and communicated to staff. Prior to the section 29 warning notice issued in October 2020, we saw no evidence to show staff were undertaking any mandatory training in key areas such as safeguarding and infection prevention and control. In response to the warning notice, we requested evidence of the training policy, including confirmation and evidence of the qualifications and training by all staff members. The service employed one sonographer and provided evidence of the sonographer's registration with the American Registry for Diagnostic Medical Sonography (ARDMS). The service stated they were unable to access their online training management system to fully clarify training records and continuing professional development (CPD) for the registered manager. The training policy was not provided. There was no breakdown of training required per employee role, although the service listed six mandatory courses including infection control, confidentiality, consent, information handling and equality and diversity.

Some staff received training in some safety systems, processes and practices.

The service submitted a training matrix and certificates which showed the sonographer had completed training in all six categories. However, we saw evidence which showed the registered manager had only competed training in infection prevention and control and safeguarding level 3. From the information sent and reviewed on site, there was little evidence (including an incomplete training matrix) that all staff had received the required training to enable them to fulfil their role in delivering safe care and treatment. There was no evidence of any basic life support training for any staff.

Safeguarding

Staff generally understood how to protect women from abuse, but we could not assess if the service worked well with other agencies to do so. Staff had training on how to recognise and report abuse but did not recognise all types of abuse.

Inspected but not rated

Diagnostic imaging

It was not clear how safety and safeguarding systems, processes and practices were developed. We reviewed information sent in response to the warning notice in October 2020 and reviewed certificates whilst on site, which showed all staff had undertaken level 3 safeguarding training. We also supplied the service with best practice guidance including the intercollegiate guidance, 'Adult Safeguarding: Roles and Competencies for Health Care Staff, First edition: August 2018' on 1 September 2020 and the safeguarding children's intercollegiate guidance 'Safeguarding Children and Young People: Roles and Competencies for Healthcare Staff, Fourth edition: January 2019.' The 'Adults at Risk Policy' provided in response to the warning notice was not specific to the service and the 'Safeguarding Children' policy was incomplete. We saw no additional evidence on site to assure us that safeguarding was understood by all staff or that a referral pathway had been established with the relevant local authority. Since the inspection, the service provided an updated safeguarding policy for children which included referral templates (for both adults and children) and details of the local authority, including telephone numbers. However, the policy was still not specific to the service and mentioned GPs' nurses and referred to the General Medical Council document "Raising and acting on concerns about patient safety," effective 12 March 2012 and did not did not mention safeguarding children's intercollegiate guidance 'Safeguarding Children and Young People: Roles and Competencies for Healthcare Staff, Fourth edition: January 2019'. The service also had not submitted a completed adult safeguarding policy specific to the service.

Safety was not promoted in recruitment practice, arrangements to support staff, disciplinary procedures, and ongoing checks. We saw evidence of an online Disclosure and Barring (DBS) check through a generic website, which clearly stated the document provided was not a DBS certificate. The registered manager told us their (DBS) application was in progress but did not provided any evidence to confirm this or that staff members have had a complete DBS check undertaken. Since the inspection, the service provided an up to date DBS certificate for all staff. However, there was no policy or checklist to provide assurance the service would carry out all necessary checks for any staff recruited in the future.

Staff did not identify adults and children at risk of, or suffering, significant harm but had just begun to work in partnership with other agencies. On this inspection, we spoke with staff who were initially not clear where or whom to direct safeguarding concerns. Policies we initially saw were incomplete and did not provide clear guidance or any details of relevant local authorities for escalation of safeguarding concerns. Staff stated they did not feel comfortable to contact other organisations for advice and did not know about open safeguarding referrals system on the local authority website. Since the inspection, the service submitted an updated policy and referral process, however, this was only for children and contained information which was not relevant or correct for the service. For example, the policy stated the safeguarding lead should be fully conversant with all aspects of the Ultrasound Baby Face child protection policy, operating procedures and incident handling procedures, but did not have an incident policy. The policy also stated where emergency medical attention was necessary it should be given, however the service has provided no training details for basic life support or first aid for any staff or a deteriorating patient pathway or policy.

The service provided ultrasound services to adolescents under the age of 18 years, but it was unclear how examinations for 16- and 17-year olds were undertaken in relation to who had to accompany the patient. Following the inspection, the service submitted an updated safeguarding policy which was nonspecific and referred to out of date guidance. The service was registered to provide services to patient from 13-18 years as well as 18-65 years. However, staff told us they did not scan anyone under the age of 16 years, although this was not recorded or defined in any documentation or in the booking terms and conditions or consent form. Since the service opened in January 2015, the service had scanned one 17-year-old patient and had received a query about a 15-year-old. Staff did not know if they should consider any safeguarding concern for a patient under the age of 16, and we saw nothing written in any policy to provide guidance or assurance. Staff were also unaware of all types of abuse including modern slavery. Staff did not recognise why some patients may seek out independent imaging services to avoid NHS pathways in certain circumstances, such as underage pregnancies.

Inspected but not rated

Diagnostic imaging

Cleanliness, infection control and hygiene

The service did not control all infection risks and staff did not use equipment and control measures to protect women, themselves and others from infection. They kept equipment and the premises visibly clean. However, we were not able to assess the governance processes to ensure the service was compliant with its own checklists as they had not yet been fully implemented.

Standards of cleanliness and hygiene maintained were maintained, however we saw no evidence of any audit to confirm staff were adhering to policy. We reviewed the statement of purpose (SOP) submitted by the service which stated internal ultrasound examinations were offered as part of the early pregnancy package. During the inspection, staff confirmed the SOP was incorrect, however, an updated version had not been supplied by the provider in response to our request in October 2020 and also post inspection. However, we spoke to staff who confirmed these examinations were not offered and we did not see any equipment in use which would allow this type of examination. Staff showed us they used anti-microbial wipes for decontamination of all external ultrasound probes and patient examination couch.

There were some systems in place to prevent and protect people from healthcare-associated infections. An infection prevention and control checklist had been developed but was not yet in use. Policies and checklists had been submitted which referenced multiple policies including transducer cleaning procedures, but the policies themselves had not been submitted, nor any audit evidence to show compliance. We spoke to staff who told us the policies were under development at the time of our inspection, but we did not see the transducer policy referred to on the checklist. We also saw a hand hygiene policy and checklist, but this too had not yet been put into use. Staff were not wearing uniform as stated in the infection prevention and control, policy.

There were systems in place to monitor risks from legionella. The Legionella risk assessment and policy detailed that the registered manager and sonographer were responsible for ongoing monitoring, but it did not state how they would monitor and how often. There was no accompanying evidence of any checks or audits had been undertaken.

Environment and equipment

The design, maintenance and use of facilities, premises and equipment kept people safe. Staff were trained to use them. Staff managed clinical waste well.

The maintenance and use of equipment kept people safe. The service used a portable ultrasound unit with 4D and 3D capability. We saw the service held a contract with a medical imaging device company for annual servicing and planned preventative maintenance. We asked to review the most recent report from the servicing engineer, but the registered manager told us it was being emailed to them on Monday. The manager told us they had received verbal assurance the equipment was safe to use. Since the inspection, the service submitted detailed servicing reports for the equipment which showed it was being maintained in line with manufacturer guidance.

The arrangements for managing waste kept people safe. The service had a waste management policy which covered all types of clinical waste. We saw a foot operated pedal bin with correct waste bags for the type of waste the service provided. No hazardous waste was produced by the service, but staff could describe how they would deal with bodily fluid spills.

The service had access to personal protective equipment, and we saw staff using this correctly. However, it was recorded in the sonographer's risk assessment that they had not received any formal training in the use of PPE.

Inspected but not rated

Diagnostic imaging

Assessing and responding to patient risk

Staff completed and updated risk assessments for each woman and removed or minimised risks. There was no policy or guidance to tell staff hat to do when there was an emergency and there was no record of any life support training or deteriorating patient policy.

Risk assessments were carried out for people who used services in relation to Covid 19. We saw patients having their temperature checked prior to admission into the clinic. We also saw as part of a new consent form, information requested about any known risks or previous ultrasound findings.

Staff could describe and identify how they would respond to changing risks to people who used services, including deteriorating health and wellbeing or medical emergencies. However, the service had no deteriorating patient policy and we saw no evidence of any life support or first aid training for any staff. This meant there was a risk that staff would not respond appropriately in the case of a medical emergency.

There was a process to escalate unexpected or significant findings at the examination. Following the warning notice issues in October 2020, the service submitted a foetal abnormality policy which described conditions which may be picked up by the sonographer, however there was no referral pathway or contact details for the local obstetric hospital. Staff told us a referral document was being developed but was not yet in use. This was not reflected in any policy. Staff explained they would obtain the patient's midwife and GP contact details to discuss any concerns. However, it was unclear when these referral calls would be made, or how this would be recorded as the clinic only operated on a Saturday at present. Currently, the sonographer explained they described the scan to the mother as they scanned, but we were told there were plans to record the observations in a report. There was also an option on the bookings system to allow a mother to add a wellbeing report to the scan package, but this was not yet taking place. Since our inspection, the service submitted a clear referral form which would be used to highlight any potential concerns to the patient GP or midwife.

Women were still advised to attend their NHS scans as part of their maternity pathway. This was reaffirmed in the booking terms and conditions. Also, the new consent form asked the mother to confirm they had already had their 12-week scan. This form was then signed by the patient prior to having their scan which we saw in use on our inspection.

Women who undertook these scans were not given information about the risks of frequent scanning and there were no limits on the number of scans an individual woman could have. The volume of patients going through the service was small. However, we did not see this recorded in any policy. Re-scanning rates were not monitored.

The service did not have a policy to respond if they had a concern, did not detect the baby's heartbeat or suspected a multiple pregnancy. The new consent form asked for any relevant information from the patient's previous ultrasound examinations such as multiple pregnancy, but this was not recorded in the foetal abnormality policy. We saw no evidence of any training in giving bad news for any staff member. Staff explained that this had not yet happened, and we had no assurance they had the necessary skills, knowledge, training or appropriate referral pathways to deal with such a situation. Since the inspection, an updated foetal abnormality policy was submitted. The policy outlined what staff should do if an abnormality was suspected. The policy also stated delivering bad news training could be arranged through the registered manager, so it remained unclear if staff had appropriate training to deliver potential bad news.

Staffing

Inspected but not rated

Diagnostic imaging

The service had some staff with the right qualifications, skills, training and experience to keep women safe from avoidable harm and to provide the right care and treatment. Managers did not review and adjust staffing levels and skill mix, and did not give bank, agency or new staff a full induction. There was no staff induction policy.

The staffing arrangements showed the service employed one sonographer and the registered manager. At the time of our inspection, the service employed no other staff.

We saw no evidence of a local induction policy for staff. We also did not see records of any training in using the ultrasound equipment, although the sonographer was an accredited diagnostic medical sonographer and had applied to the Public Voluntary Register of Sonographers, (now merged with the Register of Clinical Technologists) for further accreditation and was awaiting confirmation they had been accepted.

The sonographer worked alone in the scan room and we did not see any risk assessments to minimise risks associated with lone working.

The service had completed a COVID-19 risk assessment for staff in at risk groups. The assessment showed a staff member was from a BME background. It showed the staff member had not had any formal training in the use of PPE and was unsigned.

Following the inspection, we were provided with the policy identifying how staff could access an appropriate healthcare professional if required, such as the women's GP or midwife if there was a concern. The foetal abnormality policy described how the service would escalate any concerns, and record midwife or GP contact details. However, as the documentation to capture this had only just been developed, there was no evidence to show if it was effective or being used appropriately. There was also no policy or procedure if a patient declined to give contact details of their midwife or GP. Staff did not recognise this was a potential safeguarding concern should something be noted on the scan which required referral.

Arrangements for using bank, agency and locum staff did not always keep people safe**.** The current sonographer was due to leave the service soon, and there were currently no plans to recruit a replacement. The registered manager told us they knew of two other sonographers but did not explain how they would ensure the sonographers had all the skills, competencies and training they needed prior to working for the service and that they were if good character.

Records

Staff did not keep detailed records of women's care and treatment. Records were not stored securely.

People's individual care records, including clinical data, were not managed in a way that kept people safe. All images were stored on the ultrasound machine which the service report confirmed was not password protected, however the registered manager informed us that every scan they had undertaken since 2015 was stored here. Consent forms were stored electronically on a computer which was password protected. The service did not have an information governance policy which outlined when images or patient data should be deleted.

Inspected but not rated

Diagnostic imaging

Information needed to deliver safe care and treatment was not always available to relevant staff in a timely and accessible way. Imaging was limited to scans only taken by the service. Staff told us they were now requesting patients to bring their notes with them, however as a proportion of patients who attended for scans were walk ins, this would not always be possible. The service did not have a policy or process to manage situations where patient's notes were not available.

Enough information was obtained from the woman prior to their scan e.g. allergies or number of weeks pregnant**,** however this had only just started to happen with the introduction of the new consent form.

Incidents

The service did not manage safety incidents well. Staff did not recognise and report incidents and near misses. There was no incident policy or system to capture incidents. Managers did not investigate incidents and did not share lessons learned.

The service did not have an incident reporting policy or system and there was no information available to show us the service monitored any incidents or near misses

Are Diagnostic imaging effective?

Inspected but not rated

We did not inspect this key question but focused on those areas highlighted in the warning notice as requiring significant improvement.

The rating was not assessed as part of this inspection.

Competent staff

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

Staff who conducted scans were appropriately trained and undertook periodic accreditation with their registered board. The service provided evidence of one sonographer's registration with the American Registry for Diagnostic Medical Sonography (ARDMS) which was due to expire on 31 December 2021. The sonographer explained they had to provide evidence of continuous professional development in order to be re accredited.

Results from scans were communicated to the patient by the sonographer. At the time of our inspection, the sonographer verbally described anatomy to the patient during the scan. We were told there were plans to formalise this in the form of a technical report which would be non-diagnostic and focus on gender, gestation and basic anatomy description but there was no timeframe to show when this would be introduced.

Diagnostic imaging

There was no evidence to show scan quality was assessed by anyone other than the sonographer undertaking the scan. The registered manager reviewed images with patients from an entertainment perspective (for example, was the baby's face clearly visible). There was no established system of peer review or retrospective review of images for quality assurance.

Clinical staff undertook continuous professional development, but it was not established how the registered manager kept track of training expiry and their training needs. Also, there was no evidence of any appraisals for staff.

Consent, Mental Capacity Act and Deprivation of Liberty Safeguards

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

Women's consent to care and treatment was sought in line with legislation and guidance.The service had a comprehensive consent form for women over the age of 18, which captured information about the patient, including their GP and midwife details, previous scan history and desired outcome from the scan (i.e. gender or general entertainment).

The service scanned pregnant ladies between the ages of 16 and 17. We saw a separate consent form for these patients which allowed for a guardian to countersign the form. The Gillick consent policy stated the service must accept the consent of 16 and17 year olds if they demonstrated they were competent to make their own decisions but went on to say the consent form needed to be countersigned by a parent or guardian. This was a contradiction to the policy and showed staff were not clear around the use of Gillick Competency. Gillick competence is concerned with determining a child's capacity to consent and applies to children under the age of 16. 16- and 17-year olds are presumed in law, like adults to have capacity to consent to their medical treatment, however, unlike adults, their refusal of treatment can in some circumstances be overridden by a parent, someone with parental responsibility or a court.

The service did not ensure that women using it were informed of the limitations and risks associated with the scan, so they could make an informed decision on proceeding with the scan. The goals of the scan were set out in the consent policy which stated the scan was for non-diagnostic purposes, however we did not see any information in the consent policy or booking terms and conditions about any risks associated with repeat ultrasound scans. , The sonographer was able to explain how they used the ALARA (as low as is reasonably achievable) principle when carrying out all scans. This principle is recommended by the Society of Radiographers and also the Ionising Radiation (Medical Exposures) regulations (IR(ME)R) 2018, to help prevent overexposure of patients to investigations involving ionising radiation, however the principle is also extended to imaging which does not involve any type of radiation, such as ultrasound or Magnetic resonance imaging (MRI).

Consent was obtained to share information with the woman's GP, but we did not see on the consent form any explanation as to why this might be necessary.

The service did not have a referral pathway for women experiencing acute anxiety or mental health crises during pregnancy, although the sonographer explained that any concerns about a patient's general wellbeing were discussed with the patient's midwife or GP.

The service did not look for any red flag indicators such as repeat attendance, however as the service had been dormant during the pandemic, there had been very few patients coming through the service.

Inspected but not rated

Diagnostic imaging

Are Diagnostic imaging well-led?

Inadequate

We rated well led as inadequate because;

Governance

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

The service did not have an up to date statement of purpose (SOP) and pathway documents were not specific to the service. We reviewed the 'Patient Pathway' guidance supplied in response to the section 64 letter (issued on 2 October 2020), issued prior to this inspection. The document suggested diagnostic procedures were undertaken, which was not in line with the information previously supplied or in the statement of purpose. Following the inspection, the service submitted some updated policies including the foetal abnormality referral pathway and policy, but the SOP still did not reflect an accurate picture of what the service offered.

There was no established programme of audit to ensure policies were adhered to. In response to the warning notice issued in October 2020, the service submitted multiple checklists intended for use in internal audit. However, at the time of inspection, these had yet to be used. There was no audit plan or governance mechanism to capture audit data from these checklists.

Managing risks, issues and performance

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

The service did not have a business continuity plan. The registered manager told us losing the sonographer was the biggest risk to the business, however there was no plan and it was not clear how the ultrasound part of the business would operate if the sonographer was unavailable or off work and the service had not identified a replacement sonographer.

The service did not have a risk register or process to review risks and record any actions taken. We were not assured the service had an overarching view of risks to the business or premises and we saw no evidence to show any mitigation, action or monitoring of any risks. The service did not report or record any incidents or near misses, so we were not assured the service would be aware of any emerging risks.

The service carried out some risk assessments in relation to BME staff and Covid 19 screening for patients and visitors. The service had completed a COVID-19 risk assessment for staff in at risk groups. The assessment showed a staff member was from a BME background. However, it showed the staff member had not had any formal training in the use of PPE and was unsigned.

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 have an up to date Statement of Purpose (SOP). The SOP showed the service still offered transvaginal scans as part of its early pregnancy scan package. The patient pathway document still referenced diagnostic examinations and non-obstetric scans. There was also no business continuity plan or a record of pre employment checks the service would undertake for future staff if the current sonographer or any other staff member was off work. The service also did not have an incident reporting system or any other system to record any adverse incidents or near misses. The new safeguarding and abnormality referral processes were untested as they had been written as a response to the warning notice. The adult safeguarding policy which was submitted was incomplete, and the child safeguarding policy referenced out of date guidance and referred to staff and policies the service did not have. Consent forms labelled for use for anyone under 18 years of age stated they needed to be countersigned by a parent or guardian which contradicted the consent policy. There was no evidence of any data to support the newly developed infection prevention and control checklist or hand hygiene audit checklist as they had not yet been implemented. There was no evidence or workplace risk assessments about lone working or manual handling in relation to use of the scan equipment. There was no established job specific training matrix for all staff. The service did not supply complete training

This section is primarily information for the provider

Enforcement actions

data for any staff other than the sonographer. There was also no evidence of staff undertaking any basic life support training and there was no deteriorating patient policy.

Scan quality was not monitored and there were no audits or a system for peer review. There was no evidence the service gave or signposted women to information around repeat scans and associated risks. Images which were stored on the ultrasound machine were not password protected.