Your Baby Scan Ltd

Your Baby Scan Ltd

Inspection report

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

Ratings

Overall rating for this location	Inadequate
Are services safe?	Inadequate
Are services effective?	Inspected but not rated
Are services caring?	Requires Improvement
Are services responsive to people's needs?	Requires Improvement
Are services well-led?	Inadequate

Summary of findings

Overall summary

We rated it as inadequate because:

- We found that overall mandatory training compliance was low. It was unclear if the correct level of safeguarding training was provided to staff and staff did not always know how to recognise and report potential abuse. The service did not have effective control measures in place to protect women from infection and we found that the clinic was not always clean. We did not see evidence of equipment servicing, calibration and electrical safety checks. The service did not have policy for managing emergency situations and staff were not always aware of how they should respond if a woman became seriously unwell. The service did not have an inclusion/exclusion criteria or policy for rescan timeframes for staff to follow. Staff were not provided with incident reporting training and there was no policy for incident reporting.
- We found out of date guidance on the service intranet which could mean that staff might not have been practicing in accordance with the most up to date best practice guidance. Policies were created and reviewed without any clinical input. Outcomes and performance data were not monitored and shared with staff to measure performance and allow for improvement. The service had no induction policy and no process for checking that staff were competent for their roles. Staff did not receive training in consent to care and treatment or the Mental Capacity Act. There was no consent policy or audit of consent processes. There was also no policy for supporting women who were experiencing anxiety or mental health crisis.
- Screens and towels provided to women to maintain privacy and dignity were not fit for purpose. Women were unable to speak to reception staff without being overheard by other service users. Staff were provided with limited resources for signposting women who needed further care or support.
- The service did not always identify individual needs of women using the service and were not always able to support those women. They were no facilities available to meet the needs of service users with hearing or sight problems. Staff we spoke with were not aware that they were able to access information for those whose first language was not English. The service did not have a policy for meeting the needs of those with mental health problems or learning disabilities. The person responsible for managing and investigating complaints was not adequately trained.
- It was not clear if leaders had the skills and abilities to run the service, and they were not always aware of challenges to the quality and sustainability of the service. Staff we spoke with were not always aware of their responsibilities. The manager had no formal vision or strategy for the service. The service did not have effective recruitment processes in place to ensure that staff were competent, skilled, experienced, held a current professional registration and had the right to work. Risk assessments were not fit for purpose and not all identified mitigating actions had been completed. The service did not always keep staff safe; there was no lone working policy, no policy for the management of aggressive service users and staff had not been asked to complete individual COVID-19 risk assessments. The service did not have processes in place to effectively monitor infection control processes or equipment safety. There was no policy for the storage of scans and records and women were not informed of this in the service terms and conditions. Staff were not required to complete quality improvement training and were not provided with data to enable them to make changes or improvements to their practice.

However:

- The service had enough staff to care for women.
- Staff treated women with kindness and compassion.
- The service made it easy for women to give feedback.
- Staff felt respected, supported and valued.

Summary of findings

Our judgements about each of the main services

Service	Rating	Summary of each main service
Diagnostic and screening services	Inadequate 	We rated it as inadequate because: • We found that overall mandatory training compliance was low. It was unclear if the correct level of safeguarding training was provided to staff and staff did not always know how to recognise and report potential abuse. The service did not have effective control measures in place to protect women from infection and we found that the clinic was not always clean. We did not see evidence of equipment servicing, calibration and electrical safety checks. The service did not have policy for managing emergency situations and staff were not always aware of how they should respond if a woman became seriously unwell. The service did not have an inclusion/exclusion criteria or policy for rescan timeframes for staff to follow. Staff were not provided with incident reporting training and there was no policy for incident reporting. • We found out of date guidance on the service intranet which could mean that staff might not have been practicing in accordance with the most up to date best practice guidance. Policies were created and reviewed without any clinical input. Outcomes and performance data were not monitored and shared with staff to measure performance and allow for improvement. The service had no induction policy and no process for checking that staff were competent for their roles. Staff did not receive training in consent to care and treatment or the Mental Capacity Act. There was no consent policy or audit of consent processes. There was also no policy for supporting women who were experiencing anxiety or mental health crisis. • Screens and towels provided to women to maintain privacy and dignity were not fit for purpose. Women were unable to speak to reception staff without being overheard by other service users. Staff were provided with limited resources for signposting women who needed further care or support. • The service did not always identify individual needs of women using the service and were not always

Summary of findings

able to support those women. They were no facilities available to meet the needs of service users with hearing or sight problems. Staff we spoke with were not aware that they were able to access information for those whose first language was not English. The service did not have a policy for meeting the needs of those with mental health problems or learning disabilities. The person responsible for managing and investigating complaints was not adequately trained.

- It was not clear if leaders had the skills and abilities to run the service, and they were not always aware of challenges to the quality and sustainability of the service. Staff we spoke with were not always aware of their responsibilities. The manager had no formal vision or strategy for the service. The service did not have effective recruitment processes in place to ensure that staff were competent, skilled, experienced, held a current professional registration and had the right to work. Risk assessments were not fit for purpose and not all identified mitigating actions had been completed. The service did not always keep staff safe; there was no lone working policy, no policy for the management of aggressive service users and staff had not been asked to complete individual COVID-19 risk assessments. The service did not have processes in place to effectively monitor infection control processes or equipment safety. There was no policy for the storage of scans and records and women were not informed of this in the service terms and conditions. Staff were not required to complete quality improvement training and were not provided with data to enable them to make changes or improvements to their practice.

However:

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Summary of findings

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Summary of this inspection

Background to Your Baby Scan Ltd

Your Baby Scan Ltd runs two locations, Your Baby Scan Ltd (Widnes) and Your Baby Scan Crewe. Your Baby Scan Ltd (Widnes) registered with the Care Quality Commission in 2015. The service has had a registered manager in place since initial registration.

The service provides a range of ultrasound scans in 2D,3D and 4D for women prior to and during pregnancy for women of all ages. It is registered to provide the regulated activity of diagnostic and screening procedures.

We carried out a transitional monitoring call with the service on 1 March 2021. The transitional regulatory approach is a consistent and structured approach to monitoring and relationship management, with clear areas of focus based on a streamlined set of Key Lines of Enquiry (KLOEs), through the Transitional Monitoring Activity (TMA). Information gathered during this call prompted the need for us to inspect the service and was considered as part of the inspection process.

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How we carried out this inspection

Our inspection was unannounced (staff did not know we were coming) to enable us to observe routine activity. We inspected this service using our comprehensive inspection methodology. Two inspectors carried out the inspection on 12 April 2021 with off-site support from an inspection manager and head of hospital inspection.

On the day of the inspection, we spoke with two members of staff, the registered manager and another person involved in the business

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.

Areas for improvement

Actions the service MUST take to improve:

- The provider must ensure infection prevention and control procedures are aligned to current best practice guidelines to prevent women being exposed to unnecessary risk. (Regulation 12)
- The provider must ensure that staff continue to have the required level of training or skills to enable them to recognise the potential risk and protect vulnerable adults and children from abuse. (Regulation 12)
- The provider must have robust procedures in place for escalation in the event of an emergency and ensure staff are provided with the tools to assess and respond to women who may require urgent treatment. So that in an emergency, women are not exposed to unnecessary risk. (Regulation 12)
- The provider must have the processes in place to ensure that staff are suitably qualified, competent, skilled and experienced persons to ensure provision of a safe service. The manager must ensure that they meet the requirements of Schedule 3 of The Health and Social Care Act 2008 (Regulated Activities) Regulations 2010. (Regulation 19)

Summary of this inspection

- The provider must have effective governance processes to ensure the safe and effective delivery of care. The manager must always have oversight of risks and challenges which could cause potential harm to women who use the service. (Regulation 17)
- The provider must ensure mandatory training compliance is maintained. (Regulation 12)
- The provider must have a system in place to ensure equipment is serviced and electrical safety is monitored and recorded. (Regulation 12)
- The provider must have effective and up to date policies to support staff to deliver safe care to women. (Regulation 12)
- The provider must ensure that all staff working in the service performing the functions of a director are employed in line with schedule 3 of the regulated activities (2014) (Regulation 5)

Action the service SHOULD take to improve:

The provider should ensure that:

- The provider should ensure it supports women to maintain their privacy and dignity whilst using the service.
- The provider should ensure staff have the skills and tools to identify individual needs of women and can adapt services to meet those needs.
- The provider should ensure risk assessments are fit for purpose and that any identified mitigating actions are completed by appropriate people.
- The provider should ensure staff understand their roles and responsibilities.
- The provider should ensure it monitors women's outcomes and its own performance. This data should be used to measure the effectiveness of the service and to identify areas for change or improvement.

Following our inspection, we urgently escalated our concerns with the provider and they made some improvements. We issued the provider with a warning notice under Section 29 of the Health and Social Care Act 2008 because they were failing to comply with the relevant requirements of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014. We also issued the provider with three requirement notices with actions they must complete that affected Your Baby Scan Ltd.

We are 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 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.

Our findings

Overview of ratings

Our ratings for this location are:

	Safe	Effective	Caring	Responsive	Well-led	Overall
Diagnostic and screening services	Inadequate	Inspected but not rated	Requires Improvement	Requires Improvement	Inadequate	Inadequate
Overall	Inadequate	Inspected but not rated	Requires Improvement	Requires Improvement	Inadequate	Inadequate

Inadequate

Diagnostic and screening services

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

Are Diagnostic and screening services safe?

Inadequate

We rated it as inadequate because:

Mandatory training

- **The service provided access to mandatory training in key skills for staff. However, managers did not ensure that all staff completed it. This meant that the service could not be sure that staff had up to date training in key skills.**
- At the time of our transitional regulatory call on 1 March 2021, we were told that staff were required to complete 24 training modules. At the time of the transitional regulatory approach call, three of the four (75%) eligible people had not completed any mandatory training.
- At the time of the inspection, training figures had improved however, three eligible people had a completion rate of less than 40% and no eligible people had completed emergency first aid training. No sonographers had completed loss and bereavement awareness training.
- Managers told us staff had been given protected time to complete outstanding training. However, staff we spoke with told us that they do not have protected time and that training had to be done in between appointments.

Safeguarding

- **Not all staff understood how to protect adults and children from abuse.**
- It was not clear if staff were provided with the appropriate level of training required in line with the Safeguarding Children and Young People: Roles and Competences for Healthcare Staff Fourth edition: January 2019 intercollegiate requirements.
- Despite the service providing care for young people under the age of 18 years of age, the registered manager was not able to provide evidence that staff were trained to level three in Safeguarding Children.
- The Safeguarding Children Policy did not cover all aspects of potential abuse. For example, female genital mutilation, forced marriage and child sexual exploitation were not included.
- At the time of our inspection three eligible people (75%) had not completed any safeguarding children training and one (25%) had not completed any safeguarding adults training. We spoke to one member of staff who described a data breach as an example safeguarding concern.

- The chaperone policy did not outline the role of the chaperone in relation to staff support and protection. It also stated that a friend or family member can be a chaperone which is not in line with best practice guidelines. Staff did not understand the responsibilities of a chaperone and training was not provided.
- However, the safeguarding policies provided to staff did outline how to escalate concerns and make referrals to the local authority.
- The Adult Safeguarding Policy did include female genital mutilation, forced marriage and sexual exploitation.
- The manager was able to provide an example of when they had contacted the local authority safeguarding team for advice.

Cleanliness, infection control and hygiene

- **The service did not always control infection risk well. The service did not have effective control measures in place to always protect women from infection.**
- We found issues with the cleanliness of equipment and the environment including equipment and surfaces being visibly dusty. The gel warmer in the scan room, mop used in the clinic and carpet in the scan room were all visibly dirty. The sonographer chair in the scan room was fabric with fabric cushions. This was an infection control risk as they could not be effectively cleaned.
- We saw that staff were refilling alcohol gel and ultrasound gel bottles from larger bottles. Expiry dates of these products were not being monitored.
- The procedure for staff to follow in relation to the cleaning and disinfecting of trans-vaginal probes was not in line with British Medical Ultrasound Society (BMUS) and manufacturer guidelines. We observed staff cleaning probes with disinfectant wipes, but no other cleaning or decontamination took place. This meant women could be at risk of cross infection.
- Staff used an appointment list as a 'cleaning schedule' for each day. This did not outline the cleaning requirements and we found that staff were not always aware of their responsibilities. We reviewed 14 of these and found that they were inconsistently completed.
- The scan room did not have any hand washing facilities for staff to adequately decontaminate their hands or equipment following clinical procedures. Alcohol gel was provided but if staff needed to wash their hands, they had to leave the scan room and use the sink in the toilet or kitchen. The local IPC policy stated that 'handwashing should be done using antibacterial wash as frequent as possible'.
- The manager told us staff did not receive hand hygiene training and no audits of hand hygiene had been completed.
- There was a link on the service intranet to hand hygiene guidance. However, when we used this link, it opened up the infection control policy which made reference to the World Health Organisation (WHO) visual guide to handwashing but did not provide guidance for staff about how to effectively wash their hands.
- Visitor numbers had been increased on the day of our inspection. However, the COVID-19 risk assessment and policy had not been updated to reflect these changes. Social distancing was not always maintained. We witnessed the waiting area being used by seven people (excluding staff) which meant that social distancing could not be maintained.
- Women were not always provided with information about COVID-19 restrictions at the time of booking. The manager told inspectors that this information was given verbally if the appointment was booked by phone. However, we observed staff taking phone bookings and not providing information about COVID-19 restrictions. Staff were seen verbally asking if people had COVID-19 symptoms before they entered the clinic, but the responses were not recorded.
- At the time of our inspection, two eligible people (50%) had not completed infection control awareness training and two eligible people (50%) had not completed Coronavirus awareness and infection control training despite these being part of the mandatory training requirements.
- However, Staff had access to and used appropriate and in date personal protective equipment (PPE).
- The seating in the waiting area was made of a material that could be effectively cleaned after use.

Environment and equipment

Inadequate

Diagnostic and screening services

- **The design, maintenance and use of facilities, premises and equipment did not always keep people safe.**
- The manager was unable to show us evidence of servicing or calibration for the ultrasound machine which was in use in the clinic.
- We did not see any recorded evidence that electrical equipment was safety tested or that visual checks were performed.
- The waste bin in the scan room was not foot pedal operated and did not contain a bin liner. This bin was full of used PPE, couch roll and used transvaginal probe covers.
- We saw a yellow clinical waste/sharps bin under the couch, which was not being used and was not visibly clean.
- The storeroom in the clinic was very cluttered and space was limited.
- There was no closed bin for disposal of PPE in any area other than the scan room. Staff told us they use the open bin that was behind the reception desk.
- The service had one step down to the toilet area. This was included in the service risk assessment and was clearly marked.

Assessing and responding to patient risk

- **Not all staff knew what to do when there was an emergency.**
- The service did not have a policy for staff to follow in the event of an emergency or a woman becoming unwell. Staff were provided with basic first aid guidance, but this did not outline local escalation procedures. Not all staff that we spoke to knew how to respond appropriately in an emergency.
- There was a first aid kid readily available in the clinic and we found that all items were in date. However, we saw no evidence that this was checked regularly.
- At the time of our inspection, no eligible people had completed emergency first aid training.
- We saw one historic entry in the accident book. Staff we spoke to told us that the woman received no first aid or follow up. It was not clear from the information recorded in the accident book if this was appropriate.
- We were told by managers and staff that there was no inclusion/exclusion criteria outlining circumstances where women could or could not access the services provided.
- There was information on the service website explaining that if a woman is experiencing pain or bleeding, they should contact their NHS clinical care team. When we asked a staff member about this, they told us that if a woman calls with pain or bleeding that they would book them in for an appointment. This puts women at risk of not receiving the correct care.
- There was no policy for rescans and no guidance available to staff about timeframes between scans. We found information on the website about when women could attend for scans; including age restrictions and time between scans. However, when we spoke with staff, they told us that all requested appointments were booked unless there was no availability.
- The service did not have a policy for managing women who did not attend for their appointment. Staff told us that there is no follow up process for any potentially vulnerable women who did not attend.
- Health and safety awareness training was included in the mandatory training requirements. At the time of the inspection, two eligible people (50%) had not completed this training.
- Staff did not routinely obtain any information regarding underlying health conditions or allergies. When we asked staff about this, they were not clear about who was responsible for asking about allergies.
- We observed three scans and saw staff asking women about the stage of their pregnancy and their pregnancy history. However, we observed one scan where a woman divulged that she had experienced some symptoms in the week previous and the sonographer did not ask any questions about this.
- However, staff had access to a miscarriage and abnormalities procedure and sonographer duty of care flow chart which outlined the process they should follow in the event of an abnormality being identified. The service had template letters for staff to completed when referring onto NHS services. Contact details for the local early pregnancy assessment units were available on the service intranet.

Inadequate

Diagnostic and screening services

- The terms and conditions outlined on the consent form and information available on the service website recommended service users to continue to attend NHS appointments and scans.

Staffing

- **The service had enough staff to provide care and managers were able to adapt the clinic times according to the availability of the sonographer.**
- The manager told us that locum staff are not used and where a clinic cannot be covered by a sonographer from another site, the clinic would close.
- However, the receptionist also acted as a chaperone. When this was required, the reception would be left without staff.

Records

- **We observed staff making accurate records of women's care and treatment. The records we saw were clear, up to date, stored securely and easily available to staff providing care.**
- Records were electronic. During the inspection, we did not witness staff leaving computer screens open and unattended.
- However, record keeping was a topic covered in the mandatory training requirements, however two eligible people (50%) had not completed this training.
- Completed consent forms were stored in an unsecure filing cabinet in the storeroom which could easily be accessed by women using the quiet room/additional waiting room.

Incidents

- **The service did not have a process for the management of incidents. Not all staff knew how to recognise and report incidents and near misses.**
- The service did not have a policy and incident reporting was not covered in the mandatory training.
- When we asked about incidents, we were told there had been no incidents.
- Reporting of Injuries, Diseases and Dangerous Occurrences Regulations 2013 (RIDDOR) awareness was included in the mandatory training requirements. At the time of the inspection, two eligible people (50%) had not completed this training.
- Duty of candour was one of the topics covered in mandatory training. However, at the time of the inspection, three eligible people (75%) had not completed duty of candour training.

Are Diagnostic and screening services effective?

Inspected but not rated

We did not rate effective. We found:

Evidence-based care and treatment

- **The service did not always provide staff with access to the most up-to-date best practice guidelines. Managers did not check to make sure staff followed guidance.**
- There was no clinical input into the creation or review of policies.
- The British Medical Ultrasound Society Guidelines for Professional Ultrasound Practice available to staff on the service intranet were dated December 2018. The national guidelines have been updated in March and December 2019. This meant that staff may not be following the most up to date guidance.

Inadequate

Diagnostic and screening services

Nutrition and Hydration

- Prior to the COVID-19 pandemic, the service had offered a range of drinks and sweets to women. This facility was reduced as part of the COVID-19 risk assessment completed by the clinic. At the time of the inspection, the clinic had a water cooler which we observed women using to fill their own water bottles or using provided disposable paper cups.

Patient outcomes

- We spoke with the manager about monitoring of outcomes. There were no service level targets or performance indicators. Scan times, waiting times and outcome rates were not reviewed to monitor the effectiveness of the service.
- When we asked how the manager was assured that the sonographers provide a safe and high-quality service, they were unable to provide any evidence that they monitor this.
- Gender accuracy was not monitored by the service, but inspectors were informed by staff that they offer rescans, free of charge, if a woman highlights that they were told the wrong gender.
- There was no system for peer reviews within the service to ensure the accuracy and quality of the scans.

Competent staff

- **The service did not make sure that staff were competent for their roles.**
- We did not see evidence that staffs work and performance was appraised effectively, and that staff were provided with support and development.
- The service did not hold any records of staff qualifications in performing and interpreting trans-abdominal and trans-vaginal scans.
- We did not see any training records showing that sonographers had received training in how to use the ultrasound machine.
- We reviewed a personnel record for one member of staff and found:
- There were no references in the personnel file.
- There were no certificates to confirm staff qualifications.
- There was no record of a Disclosure and Barring Service (DBS) certificate
- There was a Curriculum Vitae (CV) however, this showed gaps in employment history.
- Managers told us they had not obtained any references for any members of staff and they did not check if staff had an up to date DBS certificates.
- The manager told us they carry out a regular review of scans to check that the required information has been included in the report. When we asked to see copies of these, they were unable to show us any. In addition, we did not see any reference to these reviews recorded on the human resources system for the sonographer.
- The service did not have a local induction policy and there were no induction records available for any staff.
- During our transitional monitoring call with the manager in March 2021, we were told that staff appraisals were completed every three months. The sonographer and the receptionist had been employed by the service for more than twelve months, but we did not see evidence of these appraisals.

Multidisciplinary working

- **Staff did not always work together or with other stakeholders to benefit women.**
- When we spoke with sonographers, they told us that they have no regular contact with the other sonographers in the service.
- The manager told inspectors that staff have access to an internal messaging system to enable them to maintain contact with other staff members. However, inspectors were told by the manager that the sonographers in the service rarely used this function.

Inadequate

Diagnostic and screening services

- The service has contact with the local hospital. The manager told us there was no formal contact process, they contact the hospital as and when needed.

Seven-day services

- This service does not provide emergency care and treatment.

Health promotion

- **Staff did not always give women practical support and advice to lead healthier lives.**
- Health promotion material such as smoking, alcohol and drug dependency during pregnancy was not displayed in the clinic.
- We observed three scans and no health promotion advice was given to the women.
- However, the clinic had information about Strep B in the waiting room and offered test kits at an additional cost to the woman.

Consent, Mental Capacity Act and DoLs

- **Staff supported women to make informed decisions about their care and treatment. Whilst there was no consent policy, staff followed national guidance to gain women's consent. However, we did not see any evidence that staff knew how to support women who were experiencing mental ill health.**
- We saw no evidence that the service had a consent policy and did not see any audit of consent forms.
- Staff did not undertake training on the Mental Capacity Act, Deprivation of Liberty safeguards or consent.
- The service had no policy or guidance for staff to follow for managing women experiencing acute anxiety or mental health crisis.
- When we spoke with staff, they did not identify repeat attendance as a red flag for a potentially vulnerable person and told inspectors that these women were classed as loyal customers.
- However, we reviewed ten completed consent forms and found that they were completed fully.

Are Diagnostic and screening services caring?

Requires Improvement

We rated it as requires improvement because:

Compassionate Care

- **Staff treated women with compassion and kindness but did not always respect their privacy and dignity.**
- During observation of a scan, we found that the privacy screen provided for women to undress behind and the disposable towel used to maintain the service user's dignity were both see through. This was highlighted to the sonographer at the time of the scan, but no actions were taken.
- Dignity, privacy and respect awareness training was included in the mandatory training requirements. At the time of the inspection, three eligible people (75%) had not completed this training.
- Women were not able to talk to staff at reception without being overheard by other people in the waiting room. There was no signage to explain that women could ask to speak with staff privately.
- However, the clinic has a separate waiting area/quiet room. Staff told us that this could be used as a quiet area for any women who were upset or distressed.

Emotional support

Inadequate

Diagnostic and screening services

- **We observed friendly, kind and caring interactions between staff and women. However, staff were not trained on how to provide emotional support to women to minimise their distress.**
- Staff told us that they do not have any options for signposting women to support services other than NHS maternity services.
- Loss and bereavement awareness was a topic covered in the mandatory training requirements. However, at the time of the inspection, no eligible people had completed this training. In addition, staff were not mindful of the emotional impact the scans they were performing may have on a woman.

Understanding and involvement of patients and those close to them

- **Staff supported and involved women to understand their condition and make decisions about their care and treatment.**
- We observed three scans; we witnessed staff supporting women and having appropriate discussions about the costs of the scans and any additional costs.
- Written information was provided to women about procedures.
- However, information regarding safeguarding from abuse was not displayed where women could see it.

Are Diagnostic and screening services responsive?

Requires Improvement

We rated it as requires improvement because:

Meeting people's individual needs

- **The service was not always inclusive and did not always take account of women's individual needs and preferences.**
- During our transitional regulatory approach call on 1 March 2021, we were told that additional needs are not discussed or considered at the time of booking.
- The service had a diversity policy, however this only covered age, race and religion. This policy did not identify all protected characteristics.
- There was no policy which outlined how the service adapts to and meets the needs of those with mental health needs or learning disabilities.
- Equality and Diversity training was included in the mandatory training requirements. At the time of the inspection, two eligible people (50%) had not completed this training.
- Staff we spoke with were not aware that they were able to access information for those whose first language was not English. Staff we spoke with told us relatives would act as interpreters where necessary. This could put vulnerable women at risk.
- The service did not have facilities to meet the needs of people with sight or hearing problems. There was not a hearing loop and no information available in accessible formats.
- However, the clinic has wheelchair access from the street and the couch in the scanning room was able to be lowered to enable easy access.

Access and flow

- **People could access the service when they needed it.**
- Women could access appointment times to suit their needs by telephone or by an online booking system. Appointments were available during evenings and weekends. Staff we spoke to told us that this system worked well.

Inadequate

Diagnostic and screening services

- On the day of the inspection, we did observe some unexpected delay with appointments. However, staff explained this to women and managed expectations.

Learning from complaints and concerns

- **It was easy for people to give feedback and raise concerns about care received. We were told by the manager the service treated concerns and complaints seriously, investigated them and shared lessons learned with all staff.**
- The person responsible for investigating and responding to complaints had not completed complaints handling awareness or duty of candour training.
- The service had a complaints policy. However, information about how to raise a complaint was not on display for women in the clinic. Service users could submit comments via the service website; however, the website did not include information informing women how complaints are managed and investigated.
- The service was not a member of the Independent Services Complaint Advisory Services (ISCAS) and did not have arrangements in place for independent review of complaints.
- Staff told us that lessons from complaints or incidents are shared on the service intranet home page and by the in-service chat function where required.

Service delivery to meet the need of the local people

- **The clinic was open six days per week, until 7pm on weekdays and 6pm on weekends to enable evening and weekend access to allow appointment flexibility for women.**

The service could be accessed by telephone, social media or by an online booking system.

Are Diagnostic and screening services well-led?

Inadequate

We rated it as inadequate because:

Leadership

- **Leaders did not demonstrate that they had the skills and abilities to run the service.**
- An individual who was involved in managing the business but who was not formally employed had no personnel file and it was unclear if any employment checks had been undertaken. However, we were told by the manager that the individual was responsible for creating and reviewing clinical policies, investigating complaints and covering reception duties.
- When we spoke with leaders, we found that they did not always understand the challenges to quality and sustainability and that they had not always identified actions to address them.
- In addition, during our transitional monitoring call in March 2021, the manager told us that there was no continuity plan in place to maintain management responsibilities when they were absent. This would not be sustainable in the long term.
- Staff were not always sure of their responsibilities.
- However, staff told us that service leaders were supportive, visible and approachable. Throughout the inspection, we saw leaders speaking with and supporting staff and women.

Vision and strategy

Inadequate

Diagnostic and screening services

- **The service did not have a formally documented vision for what it wanted to achieve and a strategy to turn it into action.**
- The manager told us that they wanted to offer affordable, good quality care but that no strategy or vision had been identified or shared with staff. In addition, there were no systems in place for the manager to measure the quality of the service other than service user feedback.

Culture

- **Staff felt respected, supported and valued. They were focused on the needs of women receiving care. The service promoted equality and diversity in daily work. The service had an open culture.**
- We witnessed staff and managers interacting well with each other.
- Although staff meetings were not held, other forms of communication were used to allow staff to raise concerns.

Governance

- **Leaders did not operate effective governance processes, throughout the service. Not all staff were clear about their roles and accountabilities and they did not have regular opportunities to meet, discuss and learn from the performance of the service.**
- The service governance processes did not support the safe and effective delivery of care. The manager had limited oversight of the concerns that we identified during the inspection.
- Processes to ensure that staff were suitably qualified, competent, skilled and experienced persons to ensure provision of a safe service were inadequate. For example, the manager had not obtained references for staff employed in the service. In addition, qualifications, DBS status and CVs had not been checked for all staff.
- On the day of our inspection, we also found that the link to the COVID-19 risk assessment in the COVID-19 policy did not work. When we asked for a copy of this, we found that it was not clear when this was due to be reviewed. However, the last review was 1 July 2020.
- The service COVID-19 policy stated that anyone who presents with COVID-19 symptoms must be 'logged and reported to the local authority'. When we discussed this with the managers, they told us they do not log this anywhere and were unaware that this was in the policy.
- There was no formal process for checking or audit process of the cleaning of the clinics. The manager told us that they visually check the cleaning sheet for the scan room, but we saw no evidence that this check or that any issues identified were recorded or acted upon. In addition, we found that the scan room was not clean.
- The manager was unable to provide evidence that they were monitoring servicing and calibration of the ultrasound machines.
- We found that electrical equipment in both clinics showed no evidence of electrical safety testing. Managers told us that PAT testing has not been completed as they perform visual safety checks on all the electrical items. However, we saw no evidence that visual checks were completed or recorded.
- There was no formal process in place for checking if staff had an up to date registration with a professional body, or that all those staff working under Verified International Stay Approvals had the required up to date documents.

Managing risks, issues and performance

- **Leaders and teams did not always have systems to manage performance effectively. They did not always identify and escalate relevant risks and issues and identified actions to reduce their impact. They did not always have plans to cope with unexpected events.**
- We reviewed the risk assessment document as part of the transitional regulatory approach and found that, whilst some risks had been identified, the actions identified to mitigate the risk had not been completed. For example, fabric

cushions, toys and bears had not been removed from the waiting and scan rooms. In addition, the risks were not rated or graded, there was no review dates for individual risks and some risks had the 'public' as action owners. For example the risk of staff or the public passing virus via iPads, the mitigation for this was - Wipe down iPad with antibacterial wipes after handling - Dry using blue-roll and dispose of immediately, the owners of the action were 'staff and public.'

- Lone working was not included in the service risk assessment and there was no lone working policy. On the day of the inspection, the receptionist was left alone in the clinic and we were informed that this was a regular occurrence.
- The service did not have a policy for management of aggressive service users despite one staff member giving us an example of having to manage an aggressive visitor.
- Staff did not have individual COVID-19 risk assessments, so managers were unaware of the individual risk of COVID-19 to staff members.
- A copy of the fire evacuation plan was not available in the clinic on the day of the inspection. The manager told us that Cheshire Fire Service visited the clinic in 2020 and made one recommendation which has since been actioned. We found that fire extinguishers did not have labels identifying when they were last tested, this had the risk of the provider not recognising they are next due for testing.
- However, we saw that the clinic had smoke detectors in the main waiting area.
- Fire safety training was included in the mandatory training requirements. At the time of the inspection, three eligible people (75%) had completed this training.
- Staff had access to all the available policies on the service intranet.
- The manager told us that any changes or updates to policies is shared on the intranet home page and by the in-service chat function.

Managing information

- **The service did not always collect reliable data and analyse it. Staff did not always have access to the data they needed, in easily accessible formats, to understand performance, make decisions and improvements. However, the information systems were integrated and secure.**
- The service did not collate performance data. For example, rescan rates and gender accuracy data.
- The service data protection policy did not include information regarding the retention of scan records for service users. They did not have a data retention policy outlining the purpose for processing personal data and retention periods and disposal methods.
- This was also not included in the terms and conditions.
- Cyber security awareness was included in the mandatory training requirements. At the time of the inspection, two members of staff (50%) had not completed this training.
- Information governance awareness was included in the mandatory training requirements. At the time of the inspection, three eligible people (75%) had not completed this training.
- However, terms and conditions were included on the consent forms which are provided to all service users.
- We found that service costs were readily available on the service website and social media.
- Leaders told us that scans are recorded and backed up each day to UK based secure cloud storage and kept for seven years.

Engagement

- **Active engagement with staff and service users to plan and manage services was limited.**
- Managers maintained open lines of communication with staff through a closed social media group. However, no staff surveys were completed to gather staff feedback.
- However, leaders told us the inside cover of photo presentation wallets encourages women to provide feedback to the service via google reviews, social media reviews or directly by email.

Learning, continuous improvement and innovation

Inadequate

Diagnostic and screening services

- **We saw no examples of continuous learning and improvement of the service.**
- Staff and managers did not undertake training in quality improvement therefore, the opportunity to identify areas for improvement was limited.
- Managers told us that following a complaint, the process for staff to follow if no fetal heartbeat was found had been changed. However, the miscarriage and abnormalities procedure and sonographer duty of care flow chart did not reflect this change.
- Performance data was not collected and made available to staff to enable them to change or improve practice.

This section is primarily information for the provider

Requirement notices

Action we have told the provider to take

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

Regulated activity	Regulation
Diagnostic and screening procedures	Regulation 12 CQC (Registration) Regulations 2009 Statement of purpose • The provider did not ensure infection prevention and control procedures were aligned to current best practice guidelines to prevent women being exposed to unnecessary risk. (Regulation 12) • The provider did not have robust procedures in place for escalation in the event of an emergency and ensure staff were provided with the tools to assess and respond to women who may require urgent treatment. So that in an emergency, women were not exposed to unnecessary risk. (Regulation 12) • The provider did not ensure mandatory training compliance was maintained. (Regulation 12) • The provider did not have a system in place to ensure equipment was serviced and electrical safety was monitored and recorded. (Regulation 12) • The provider did not have effective and up to date policies to support staff to deliver safe care to women. (Regulation 12)

Regulated activity	Regulation
Diagnostic and screening procedures	Regulation 5 HSCA (RA) Regulations 2014 Fit and proper persons: directors • The provider did not ensure that all staff working in the service performing the functions of a director were employed in line with schedule 3 of the regulated activities (2014) (Regulation 5)

Regulated activity	Regulation

This section is primarily information for the provider

Requirement notices

Diagnostic and screening procedures

Regulation 13 HSCA (RA) Regulations 2014 Safeguarding service users from abuse and improper treatment

The provider did not ensure that staff had the required level of training or skills to enable them to recognise the potential risk and protect vulnerable adults and children from abuse.

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 provider did not have effective governance processes to ensure the safe and effective delivery of care. The manager did not always have oversight of risks and challenges which could cause potential harm to women who use the service. (Regulation 17)