Baby Ultrasound Clinic Wakefield Limited

Baby Ultrasound Clinic Wakefield

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?	Insufficient evidence to rate
Are services responsive to people's needs?	Inadequate
Are services well-led?	Inadequate

Summary of findings

Overall summary

We carried out a comprehensive inspection of this service on the 17 May 2022, as the service had not been inspected previously. At this inspection we found significant safety concerns across all domains in which we regulate. Due to the concerns, we used our powers under Section 31 of the Health and Social Care Act 2008 to take immediate urgent enforcement action and suspended the service. This action prevented the provider from undertaking activity which put people at risk and to make immediate improvements to governance and oversight. The principles we use when rating providers requires CQC to reflect enforcement action in our ratings. The conditions we imposed have limited the rating of the safe and well-led key questions to a rating of inadequate. This means the provider has been rated as inadequate overall.

We rated it as inadequate because:

- The service did not provide mandatory training in key skills. Staff did not have the appropriate accredited safeguarding training or know how to recognise and report abuse.
- The service did not control infection risk well and some equipment was visibly dirty.
- Staff did not always identify, complete or escalate relevant risks for woman using the service.
- Staff did not always keep detailed records of women who used the service, care and procedures. Some records were illegible.
- The service did not have a clear process for the management of incidents. Staff were not trained in how to recognise and report incidents and near misses.
- The service did not provide staff with access to the most up-to-date best practice guidelines and managers did not check to make sure staff followed guidance.
- The service did not collect any outcome data or monitor the effectiveness of care.
- The service did not make sure staff were competent for their roles.
- Staff did not always give women who used the service practical support and advice to lead healthier lives.
- Staff did not receive training in how to support women to make informed decisions about their care and did not always understand how to appropriately gain consent for their care and treatment.
- The service was not inclusive and did not always take account of women using the service individual needs and preferences.
- Staff were not trained on how to provide emotional support to women who were distressed.
- Complaints were not appropriately investigated and actions were not always taken to prevent similar complaints happening.
- Leaders did not always demonstrate that they had the skills and abilities to run the service and did not operate effective governance processes.
- Leaders and staff did not always discuss and learn from the performance of the service.
- Leaders did not always have systems to manage performance effectively. They did not always identify and escalate relevant risks and issues and identify actions to improve the service.
- We saw no examples of continuous learning and improvement of the service.

Summary of findings

Our judgements about each of the main services

Service	Rating	Summary of each main service
Diagnostic imaging	Inadequate 	Please see the summary above.

Summary of findings

Contents

Summary of this inspection

Background to Baby Ultrasound Clinic Wakefield

Baby Ultrasound Clinic Wakefield is privately operated by Baby Ultrasound Clinic Wakefield Limited and registered with the Care Quality Commission in 2020. The service has had a registered manager in place since initial registration.

The service provides a range of diagnostic ultrasound scans in 2D, 3D and 4D during pregnancy, keepsakes and gender reveal souvenirs. The service provides scans for women aged 16 years and over and serves both the local community and patients from outside the area.

It is registered to provide the regulated activity of diagnostic and screening procedures.

The service employs two sonographers and a receptionist.

How we carried out this inspection

The team inspecting the service comprised of two CQC inspectors. The inspection was overseen by Sarah Dronsfield, Head of Hospital Inspection.

Our inspection took place between 17 May 2022, using our comprehensive inspection methodology. The inspection was short notice to enable us to observe routine activity, however the sonographer was not available to carry out any scans on the day of inspection. We requested patient contact details to enable us to seek the views of women who use the service, but these were not provided. We looked at thirteen sets of patient records and three staff files. We spoke with the registered manager and the receptionist.

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

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

Areas for improvement

Action the service MUST take to improve:

- The provider MUST complete appropriate checks and maintain records of the registered manager in line with the requirements of Schedule 3 and Schedule 4: Part 2 of The Health and Social Care Act 2008 (Regulated Activities) Regulations 2014. (Regulation 7)
- The service MUST ensure there is an up to date consent policy for both adults and children and ensure regular checks are carried out to make sure it is being followed. (Regulation 11)
- The service MUST ensure that identification checks are carried out for 16-18 yr olds. (Regulation 11)
- The service MUST ensure that staff undertaking the role of chaperone are appropriately trained to undertake this role. Regulation 11.
- The service MUST ensure that mandatory training in key skills is available, particularly safeguarding, capacity and consent. (Regulation 12(1))

Summary of this inspection

- The service MUST have the processes in place to ensure that staff are suitably qualified, competent, skilled, and experienced to ensure provision of a safe service. Regulation 12(2)(c)
- The service MUST ensure that all equipment conforms to the relevant safety standards. It must be regularly serviced and maintained in accordance with the manufacturer's guidance. Regulation 12(1)(2)(b)(e)(f)
- The service MUST identify, assess and record all risks including clinical and environmental risks to the health and safety of service users of receiving the care or treatment. So that in an emergency, women are not exposed to unnecessary risk. Regulation 12(1) (2a) (2b)
- The service MUST have a written standard operating procedure and protocols for staff to follow, when women present to the clinic with abnormal or concerning symptoms (Regulation 12(1))
- The service MUST ensure that all training records are up to date and have a system in place to make sure all staff have the relevant up to date registrations, skills, and competencies for their role (Regulation 12(2)).
- The service MUST ensure there is a process for ensuring and recording that all staff have undergone an annual appraisal. (Regulation 12(2)
- The service MUST ensure that there is a robust process in which incidents are clearly identified, recorded and investigated (Regulation 12 (1)).
- The service MUST ensure there is an up to date written safeguarding policy in place for staff to refer to. (Regulation 13(3)).
- The service MUST ensure staff responsible for safeguarding lead roles have the correct level of safeguarding training (Regulation 13 (1)).
- The service MUST ensure staff are able to demonstrate they would recognise possible abuse and be clear about who should be contacted if there is a concern about a person being the victim of abuse. (Regulation 13)
- The service MUST ensure all staff have the correct disclosure and barring checks in place. (Regulation 13)
- The service MUST make sure premises and equipment used, where care and treatment are delivered are clean and suitable for the purpose intended. (Regulation 15)
- The service MUST ensure that all complaints are managed in accordance with service policy. (Regulation 16)
- The service MUST maintain accurate, complete, and clear records in respect of each service user, including identification checks and clear recorded outcomes of each scan. (Regulation 17 (1)(3))
- The service MUST ensure systems or processes are established, operated and audited effectively to ensure compliance with the requirements to assess, monitor and improve the quality and safety of the services provided in the carrying on of the regulated activities (Regulation 17 (1)(3))
- The service MUST develop a specific process to ensure all scan images are reviewed and audited to ensure the quality and clarity of images undertaken. (Regulation 17 (1)(3))
- The service MUST ensure systems or processes are established and operated effectively to ensure compliance with the requirements to assess, monitor and mitigate the risks relating to the health, safety and welfare of service users and others who may be at risk which arise from the carrying on of the regulated activities. (Regulation 17 (1)(3))
- The service MUST develop a chaperone policy for the service and further develop the safeguarding policy to clearly identify the safeguard lead within the service. (Regulation 17(2)(d))
- The service MUST develop an exclusion criteria or other method of being clear about which patients' they accept into the service. (Regulation 17(2)(d))
- The service MUST develop a process to ensure staff have access to up to date evidence-based policies and procedures, which are regularly reviewed in accordance with best practice and national guidance. (Regulation 17(2)(d)).
- The service MUST ensure the clinic has robust fire safety processes in place including regularly reviewed fire risk assessments. Regulation 17(2)(b)
- The service MUST ensure that staff received appropriate support, training, professional development, supervision and induction as is necessary to enable them to carry out the duties they are employed to perform. (Regulation 18(2)(a))

Summary of this inspection

- The service MUST ensure systems or processes are established and operated effectively to ensure staff are recruited in full accordance with Schedule 3 of The Health and Social Care Act 2008 (Regulated Activities) Regulations 2014 (HSCA regulations) (Regulation 19).
- The service MUST ensure there is a Duty of Candour policy in place which describes the actions staff need to take if things go wrong in relation to care or treatment. (Regulation 20.1)

Action the service SHOULD take to improve:

We told the service that it should take action 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.

- The service should consider how it could promote its services to minority groups to ensure its services are accessible to diverse groups.
- The service should review its audit programme to ensure it can demonstrate achievement of safe standards and how it can use this information to make improvements over time.
- The service should consider additional training for staff in relation to learning disabilities and mental health.

Our findings

Overview of ratings

Our ratings for this location are:

	Safe	Effective	Caring	Responsive	Well-led	Overall
Diagnostic imaging	Inadequate	Inspected but not rated	Insufficient evidence to rate	Inadequate	Inadequate	Inadequate
Overall	Inadequate	Inspected but not rated	Insufficient evidence to rate	Inadequate	Inadequate	Inadequate

Inadequate

Diagnostic imaging

Safe	Inadequate
Effective	Inspected but not rated
Caring	Insufficient evidence to rate
Responsive	Inadequate
Well-led	Inadequate

Are Diagnostic imaging safe?

Inadequate

We rated it as inadequate.

Mandatory training

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

Staff did not receive or keep up to date with mandatory training. The mandatory training was not comprehensive and did not meet the needs of women and staff.

The provider did not have a mandatory training policy to define what the training requirements were for staff working within the clinic.

We saw some training certificates for some staff, but training arrangements were not reviewed by the registered manager and therefore the training completed was inconsistent.

One sonographer had completed overseas training for clinical sonography; however, this had not been verified or checked to ensure it meet the equivalent qualification standards to practice in the UK. Another sonographer had completed a cardiology sonography qualification, but it was not clear what training they had received, which was relevant to their current role. The registered manager told us this was not checked.

Managers did not monitor mandatory training or alert staff when they needed to update their training.

The registered manager told us they did not have any process to monitor training and was unclear as to what training staff currently held. This posed a risk to women using the service as staff may not be competent to carry out their role. Therefore, we were not assured that the service provided or supported staff with mandatory training in key skills.

Safeguarding

Staff did not understand how to protect women from abuse and the service did not work with other agencies to do so. Staff had training on how to recognise and report abuse, however they did not know how to apply it.

Staff did not always receive training specific for their role on how to recognise and report abuse.

The provider had safeguarding policies for both adults and children, but these were both out of date. The registered manager told us that they had received safeguarding level three training by an external company. We reviewed the certificate, but it was not clear if this was adult or children's safeguarding training. It was also unclear as to who was the lead for safeguarding as one policy made reference to a third party, whilst another policy stated it was the registered manager.

We saw one of the sonographers had undertaken level two adults safeguarding training, but no training was evident for the second sonographer. The receptionist had undertaken level two children's safeguarding training. None of this training had been reviewed or refreshed by the provider.

Staff could not give examples of how to protect women from harassment and discrimination, including those with protected characteristics under the Equality Act. We asked the registered manager and the receptionist for examples of how they have applied safeguarding principles and legislation to protect women accessing the services. Both were able to describe service users who may be vulnerable, but they were not able to demonstrate an understanding of protected characteristics.

The registered manager was able to provide examples of vulnerable women whom had used the service but was unable to explain what additional steps had been taken to protect and support these women.

None of staff we spoke with had raised a safeguarding alert but told us they would contact the local authority if they had any concerns.

Staff did not follow safe procedures for children visiting the service / department. We asked staff to explain what the processes are for children aged 16 yrs and over, using the service. Staff told us that identification checks had been introduced in the week before the inspection visit and all children attended with a parent or responsible guardian. We reviewed three records of children whom had been scanned within the last 12 months and saw that no identification checks had been undertaken for the child or the accompanying adult.

The provider did not have a chaperone policy and the receptionist who acted as chaperone had not been trained to carry out this role.

This posed a risk staff would not correctly identify those at risk of exploitation and we were not assured that staff understood how to protect women and children from abuse or potential abuse.

Cleanliness, infection control and hygiene

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

Clinical areas were not always clean including the equipment that was used to perform scans. We reviewed the scanning room and saw some visible dirt and dust on the scanning equipment. The receptionist told us that the room was cleaned every day it was used and this included the cleaning of equipment.

We saw that cleaning check lists had been completed for the scanning room, however there was no instruction as to how and when the equipment would be cleaned.

The provider had a deep cleaning check list also, which was up to date. We requested the providers deep clean policy to check that the deep clean process was thorough, but the registered manager told us that they did not have one.

We saw the provider was using bleach to clean areas of the clinic. We reviewed COSHH risk assessments, but they were not dated and had not been shared with the staff using the substance.

We requested hand washing audits, but the provider told us they did not have them or audit handwashing practice.

We asked to review any additional COVID-19 processes and the provider told us that they had restricted the numbers of individuals coming into the clinic. The provider also told us that they would ask service users prior to their appointment if they were experiencing any symptoms, however we did not see any evidence of this as there was no policy or record of these discussions.

The lack of adequate cleaning processes posed a risk to individuals using the service. We brought this to the immediate attention of the provider.

It was not possible to observe clinical practice as there were no clinical staff carrying out regulated activities at the time of the inspection. We requested to speak with clinical staff following the inspection, but we were not provided with any contact details to do so.

Environment and equipment

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

The design of the environment followed national guidance. The approach and entrance to the location was bright and airy. There was some information for expectant mums in the waiting area and adequate comfortable seating.

The premises were wheelchair accessible as it was located on the ground floor. There was parking close by and the premises was clearly signposted.

Staff did not always carry out daily safety checks of specialist equipment. We reviewed equipment service logs and found that these were up to date however the scanning couch service certificate was found to have expired in August 2021.

We did not see any evidence of sonographer training to use the scanning machines. The sonographer was unavailable on the day of inspection and we requested contact details but these were not provided.

We saw the fire exit to the rear of the location was kept locked. Staff were instructed locally to unlock this door during clinic opening times, but we saw clutter in and around the fire exit route. A fire risk assessment had been completed but was out of date. This posed a risk to individuals using the service and therefore we were not assured that the environment and equipment was safe to undertake regulated activities.

Staff disposed of clinical waste safely. We saw processes were in place to ensure clinical waste was disposed of appropriately.

Assessing and responding to patient risk

Staff did not complete risk assessments for each woman or remove or escalate risks.

Inadequate

Diagnostic imaging

The provider told us that they did not undertake diagnostic scans and purely carried out souvenir and gender reveal scanning. However, we reviewed the scanning reports of 13 women and saw that measurements of the foetus were taken and recorded as part of the sonographer's reports.

Staff did not know about or deal with any specific risk issues. We asked the provider what risks were assessed when booking expectant mums, but both the registered manager and the receptionist were not able to identify risk.

We saw in several reports that some women had told the provider at the point of booking, that they were experiencing heavy bleeding and clotting. These women were not escalated or signposted towards emergency services and there was no evidence of any discussion to advise these women appropriately.

We saw no medical assessment or risk consideration when booking women for the different scans. Some women could book a scan through a third party offer site, which potentially could be purchased using a false name. At no point was the identity of women checked and therefore the provider did not hold or monitor women who had received several scans and were therefore at risk of excessive ultrasound scanning exposure.

We saw several concerns expressed as complaints by women whom had used the service. Some women stated that they had been given the incorrect gender or had been told they had miscarried wrongly. We asked the registered manager if scan images were checked by another sonographer or escalated at the sonographer's request. We were told that they were checked, however there was no record or evidence of this.

We were unable to speak to any clinical staff in relation to their understanding of the management of clinical risks.

Staff did not share key information to keep women safe when handing over their care to others. Staff told us that reports were given to the women following their scan but were not sent to associated health care professionals such as GP's and midwives.

Therefore, we were not assured that staff identified or escalated risk appropriately which posed a significant risk to women using the service.

Staffing

The service had enough staff however, they did not have the right qualifications, skills, training and experience to keep women safe from avoidable harm and to provide the right care. Managers did not give staff a full induction.

The clinic employed a receptionist and two sonographers. The registered manager was also the nominated individual and service director. We reviewed the staffing files for three of the four staff, as one member of staff (the second sonographer) did not have a file in place. We saw files were not consistently completed and training completed varied, in the absence of a standardised a mandatory training system. Both sonographers held sonography qualifications, however there was no evidence to demonstrate that these qualifications were appropriate to the current role. One of the sonographers had completed cardiology sonography training and the other trained oversees.

Some staff had completed training undertaken prior to commencement at the clinic but there was no process or policy to define when this should be refreshed. We saw training certificates that had no date and the provider was unable to evidence when the training was completed.

Inadequate

Diagnostic imaging

We requested evidence of disclosure and barring checks (DBS) for all staff employed at the clinic. We saw the main sonographer did not have a check in place and the receptionist was able to provide an undated screenshot which did not show whether the disclosure was enhanced. The DBS had been undertaken for a different job role and was not applicable to the current role at the clinic.

We reviewed the providers recruitment policy which states that staff receive three different types of induction, depending on their role. We asked for evidence of these inductions as they were not within the staff files. The registered manager told us they were not completed. We were not assured that the staff working at the clinic had the correct qualifications, skills or vetting checks in place and we brought this to the immediate attention of the provider during the inspection.

Records

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

All bookings were managed through a central electronic booking system. We reviewed the system and saw that details held consisted only of a name, address and date of birth.

We reviewed the sonographers reports in which required the sonographer to state the overall outcome of the scan alongside the details of which type of scan was undertaken. In six of the seven records we reviewed, the outcome was illegible.

Records were not audited and although forms were generic for each woman, they were not checked to ensure they were fully or correctly completed.

We saw scan images were stored on encrypted memory sticks, which were deleted from the stick and stored securely within the central electronic database, following every clinic session.

Medicines

The clinic did not store or administer medicines at the location.

Incidents

The service did not manage safety incidents well. Staff did not recognise and reported incidents and near misses. Managers did not investigate incidents or shared lessons learned with the whole team and the wider service.

Staff did not know what incidents to report and how to report them. We requested a copy of the providers clinical incident reporting policy and saw that it was out of date. We did not see any evidence of staff training in relation to the management of incidents.

The provider told us they did not have an incident log as they had never had any incidents. We reviewed the providers complaints book and saw several incidents which had not been categorised as incidents. These included wrongly diagnosed miscarriage and allegations of poor staff competency.

Managers did not investigated incidents thoroughly and the incidents noted above were not investigated as incidents. We requested the response the women received from the service, but we did not receive it.

Inadequate

Diagnostic imaging

We brought this to the immediate attention of the registered manager who was unable to provide assurance that they had sufficient understanding of incidents. This posed a risk to the women using the service as future potential future incidents may not be identified, investigated or mitigated, to prevent future incident.

We were not able to speak to clinical staff to gain their understanding of the management of incidents.

Are Diagnostic imaging effective?

Inspected but not rated

Evidence-based care and treatment

The service did not provide care and procedures based on national guidance and evidence-based practice. Managers did not check to make sure staff followed guidance. Staff did not protect the rights of women subject to the Mental Health Act 1983.

Staff did not follow up-to-date policies to plan and deliver high quality care according to best practice and national guidance. We reviewed 31 policies covering both clinical and operational functions of the service. Of the 31 we reviewed, only one was found to be in date. The British Medical Ultrasound Society Guidelines for Professional Ultrasound Practice displayed in the clinic were out of date. We saw policies relating to ultrasound guidelines were also out of date. In addition, policies that we looked at, for example the infection control and safeguarding policies, did not reference evidence based best practice guidance and did not all have review dates. This meant that staff may not be following the most up to date guidance and therefore posed a risk to the women using the service.

Patient outcomes

Staff did not monitor the effectiveness of care. They did not use the findings to make improvements or achieve good outcomes for women.

Outcomes for women were not collated or reviewed. The service did not provide audit activity at the clinic, but this was not provided. 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.

The registered manager told us that scan images were sent to a third-party sonographer for a quality review, but was unable to provide any evidence in relation to this or tell us how this

information was used to improve the service.

Competent staff

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

The registered manager told us that there was currently no system in place to ensure staff were competent to undertake their role. A third-party provider arranged for a relief sonographer to cover in the absence of the usual sonographer, however no checks had been undertaken to ensure that this member of staff was suitability skilled and competent to undertake the role.

The service had an induction plan for new staff, however, there was no evidence to show that these inductions had been competed for any of the staff employed at the clinic.

Managers did not identify poor staff performance promptly or supported staff to improve. We saw within the providers complaints file, that there had been two mis gendered complaints and six image quality concerns. None of these concerns had been documented as discussed with the relevant sonographer to enable learning or identify if further training was required.

We requested supervision and appraisal documentation for all staff and saw only one sonographer had received any form of supervision. There were six supervision documents relating to meetings with this member of staff which were recently dated, but they had not been signed.

Multidisciplinary working

Staff worked together but did not work with other stakeholders to benefit women.

The provider had collated a file showing which patients had been referred to the NHS for further follow up. This information, however, was not reviewed to identify any themes and none of the information held was used to shape future services or benefit the women using the services.

The registered manager was not able to provide any evidence of team meetings to share information and also was not able to describe how the staff working at the clinic liaised with other health care professionals to further support the women who used the services.

Seven-day services

Services were available subject to staff availability

The registered manager told us that all clinic bookings were made through a central electronic database which was operated by a third-party provider. On the day of inspection, the sonographer due to carry out the scans was not available to work which resulted in all bookings for that day being cancelled at short notice. We saw some appointments had not successfully been cancelled as women and their families arrived for their scans despite there being no sonographer.

We asked when the clinic would be open in the forthcoming weeks, but staff were unsure as to which days they would be operational due to sonographer availability. The clinic had also been closed on a number of occasions due to staff ill health.

The service did not provide data in relation to the clinics usual working hours.

Health promotion

Staff gave women limited practical support and advice to lead healthier lives.

The service displayed a smoking cessation poster in the waiting area of the clinic, however there was no other health promotion information provided.

The service did not provide examples of health promotion or support.

Inadequate

Diagnostic imaging

Consent, Mental Capacity Act and Deprivation of Liberty Safeguards

Staff did not support women to make informed decisions about their care. They did not follow national guidance to gain women's consent. They did not know how to support women who lacked capacity.

Staff did not understand how and when to assess whether a patient had the capacity to make decisions about their care. We reviewed the providers mental capacity policy and found this to be the only policy in date. However, staff were unable to describe how they would apply the principles of the act or describe the legislation in which the act relates to. Staff were unable to describe how they have supported women whom may have lacked capacity.

The service had a consent policy in place; however, it had not been reviewed since 2020.

Staff did not receive or keep up to date with training in the Mental Capacity Act and Deprivation of Liberty Safeguards. Staff did not receive training in consent, the Mental Capacity Act or Deprivation of Liberty Safeguards. We asked the registered manager about this however they were unable to differentiate between the Mental Health Act and the Mental Capacity Act.

Staff did not gain consent from women for their care and treatment in line with legislation and guidance. The service accepted scan bookings for 16-18yr olds. We asked the registered manager to describe the additional considerations and checks which should be in place when consenting children.

Staff did not record consent in the women's records. The registered manager told us that two signatures were obtained when consenting 16-18yr olds, however this procedure had just been introduced very recently at the clinic. We reviewed the records of three children and saw only one signature in place.

Family members acted as interpreters when consent was gained. Staff told us that this was normal practice. This is not in line with best practice and therefore women and children may be at risk of coercion or manipulation.

Are Diagnostic imaging responsive?

Inadequate

We rated it as inadequate.

Service delivery to meet the needs of local people

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

The service offered scan appointments at evening and weekends to accommodate the needs of people who worked Monday to Friday. However, this was subject to staff availability.

The clinic was easily accessible by public transport and there was free parking available on nearby streets.

We requested information regarding numbers of missed appointments and how these were managed by the clinic, but it was not provided.

Inadequate

Diagnostic imaging

Meeting people's individual needs

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

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

Staff did not receive training in equality, diversity and inclusion and not all staff were aware of protected characteristics and their responsibilities in line with the Equality Act 2010.

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

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

The service did not have information leaflets available in languages spoken by the women and local community.

Staff did not support women with additional needs such as learning disabilities or mental health issues. We saw staff had not received any specialist training in these areas.

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

Access and flow

People could access the service when they needed it.

Women were guided to a centralised third-party booking system in which to book their scans. The registered manager told us that on occasion, appointments could also be booked in person or by telephone.

Staff told us that the appointment booking system worked well.

We requested information regarding cancelled appointments and how these were managed, but it was not provided.

We requested information regarding waiting times, but it was not provided.

Learning from complaints and concerns

Complaints were not appropriately investigated and lessons learned were not shared with all staff.

The service did not clearly display information about how to raise a concern in patient areas.

We saw the provider had a complaints policy; however, it was out of date.

We saw the provider had a book in which complaints and concerns were recorded. We reviewed this book and saw 11 complaints were received between the dates of Nov 2020 to April 2022.

Inadequate

Diagnostic imaging

Complaints included the lack of compassion given to women who were receiving distressing news, mis diagnosed gender scans and poor image quality. The registered manager told us that complaints were submitted to a third-party service to enable a formal response to be sent to the complainant. The service was unable to provide evidence of these responses for the complaints that we reviewed.

The provider did not have a policy in relation to duty of candour. Staff told us they understood duty of candour and we saw apologies had been offered to women informally. However, the provider did not review complaints to identify themes and there was no evidence of learning as a result of them.

We were unable to speak with clinical staff regarding complaints management and the provider was not able to give examples of how they used patient feedback to improve daily practice.

Therefore, we were not assured that staff understood the policy on complaints or knew how to handle them.

Are Diagnostic imaging well-led?

Inadequate

We rated it as inadequate.

Leadership

Leaders did not have the skills and abilities to run the service. They did not understand or managed the priorities and issues the service faced.

The registered manager did not understand the challenges to safety, quality and sustainability and had not always identified actions to address them.

A third-party provider had given guidance and instruction to the service in regard to the recruitment and vetting of staff. These instructions had not been followed and the registered manager did not demonstrate that they understood the importance of robust vetting and checking of staff at the point of recruitment.

The registered manager did not display the registration certification for the service, as required as part of the regulation and told us they were not aware of this.

The registered manager did not show that they understood their role in keeping people safe and in meeting the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014. We asked the registered manager about their understanding of their responsibilities as the registered manager role, but they were unaware of this and the remit of their registration.

The registered manager told us no diagnostic scans were being undertaken, however we reviewed reports which showed that diagnostic measurements were included as part of the report.

The registered manager was unable to describe the priorities for the service or describe future plans. There were no plans to develop staff skills or succession planning to support the continuation of the service in the future.

The registered manager did not hold any relevant material qualifications to support them in the running of the service.

Inadequate

Diagnostic imaging

Vision and Strategy

The service did not have a vision for what it wanted to achieve and a strategy to turn it into action, developed with all relevant stakeholders.

The service did not provide a strategy or vision for the service.

Culture

The service did not promote equality and diversity in daily work or provide opportunities for career development.

We were unable to speak with all staff employed by the service.

Governance

Leaders did not operate effective governance processes, throughout the service and did not have regular opportunities to meet, discuss and learn from the performance of the service.

The registered manager told us that they were not aware of their responsibilities when running the clinic, as they had been taking guidance from a third-party provider in relation to governance processes.

The providers own recruitment policy had not been followed, resulting in staff working at the clinic without the necessary safer staffing recruitment checks in place or verification that staff were appropriate for their role. This included the registered manager who did not have the appropriate recruitment checks in place.

The registered manager had no oversight of staff training and was unable to describe the clinics safeguarding responsibilities.

None of the sonographer's qualifications obtained overseas had been verified, to ensure they were appropriate and competent to undertake their clinical role.

Children were not consented appropriately and vulnerable women were not protected at any point when accessing the services at the clinic.

When women did speak out to raise concerns, these complaints were not investigated or taken seriously by the clinic.

We saw concerns relating to staff clinical competencies and a lack of emotional support provided to women. None of these concerns were discussed with staff and there was no evidence of additional training for staff to improve women's experience of the service.

Policies were not systematically reviewed to ensure they were reflective of best practice and national guidance or kept in date.

Not all equipment was found to have up to date service checks in place and fire safety risk assessments and fire safety management did not keep people safe.

Inadequate

Diagnostic imaging

Management of risk, issues and performance

Leaders and teams did not use systems to manage performance effectively. They did not identify or escalate relevant risks and issues. Staff contributed to decision-making to help avoid financial pressures compromising the quality of care.

The provider did not recognise risk. They did not have any risk identification process in place at the time of inspection. The service did not provide a copy of the providers risk register.

Incidents were not recognised and opportunities to investigate and mitigate against further incidents were missed, posing a significant risk to women using the services.

Women presenting with clinical concerns at the point of booking, were not escalated or directed in a timely manner. This posed a risk of harm that women requiring emergency care were not seen when needed.

Information was not held in order to identify women whom may be at additional risk, due to excessive ultrasound exposure. This risk was not understood by the clinic staff.

Performance of staff was not managed and staff did not come together to discuss operational issues and how services could be potentially improved.

The service was unable to provide feedback data from women whom had attend the clinic or any outcome data in which to drive improvement.

The service was unable to provide data regarding the numbers of women and children who have attended the clinic in the last twelve months.

Information Management

The service did not collect reliable data or analyse it. However, information systems were secure.

The service did not provide any examples of data collection or analysis. We requested to speak with staff employed at the clinic in relation to data management, but the provider did not engage with this request.

We saw scan images were stored securely and the electronic data base in which women's information was stored was password protected. Paper records were kept locked at all times.

Engagement

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

The service did not provide examples of engagement and collaboration with partner organisations.

Learning, continuous improvement and innovation

The service did not provide examples of learning, continuous improvement and innovation.