

Miracle Inside UK Ltd

Quality Report

Miracle Inside 3D/4D Baby Scan Centre,
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This report describes our judgement of the quality of care at this location. It is based on a combination of what we found when we inspected and a review of all information available to CQC including information given to us from patients, the public and other organisations

Ratings

Overall rating for this location	Good	
Are services safe?	Good	
Are services effective?		
Are services caring?	Good	
Are services responsive?	Good	
Are services well-led?	Good	

Mental Health Act responsibilities and Mental Capacity Act and Deprivation of Liberty Safeguards

We include our assessment of the provider's compliance with the Mental Capacity Act and, where relevant, Mental Health Act in our overall inspection of the service.

We do not give a rating for Mental Capacity Act or Mental Health Act, however we do use our findings to determine the overall rating for the service.

Further information about findings in relation to the Mental Capacity Act and Mental Health Act can be found later in this report.

Summary of findings

Overall summary

Miracle Inside UK Ltd is operated by Miracle Inside UK Ltd.

We inspected this service using our comprehensive inspection methodology. We carried out the inspection on 29 March 2019. Our inspection was unannounced (staff did not know we were coming).

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

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

We rated this service as **Good** overall and found the following areas of good practice:

- The service had enough staff with the right qualifications, skills, training and experience to keep people safe from avoidable harm and to provide the right care.
- Managers appraised staff's work performance annually and checked to make sure staff had the right qualifications and professional registration for their roles.
- The environment was appropriate and met the needs of the range of people who accessed the service.
- The service provided care and treatment based on national guidance and could evidence its effectiveness.
- Women could access services and appointments in a way and at a time that suited them.
- The service treated concerns and complaints seriously. The registered manager completed comprehensive investigations and shared lessons learnt with all staff.

- Staff were caring, compassionate, and kind, and engaged well with women and their families.
- The service took account of service users' individual needs.
- Managers promoted a positive culture that supported and valued staff. Staff reported that their team worked well together, and they trusted and respected each other.

However, we also found the following areas the service provider needs to improve:

- The service did not control all infection risks effectively.
- Managers did not provide evidence that they monitored the effectiveness of care and treatment and used the findings to make improvements.
- Managers did not provide evidence that they evaluated images to ensure they were of good quality.
- The service did not collect, analyse, manage, and use information to support all its activities.
- The service had not completed a risk register and did not evidence the management of risks, for example, looking after children during procedures.
- Some policies and procedures were not dated and were not specific to this organisation.
- Following this inspection, we told the provider that it should make some improvements, even though no regulation had been breached, to help the service improve. Details are at the end of the report.

Ann Ford

Deputy Chief Inspector of Hospitals (North)

Summary of findings

Our judgements about each of the main services

Service

Diagnostic imaging

Rating

Good



Summary of each main service

This is a diagnostic imaging service run by Miracle Inside UK Limited. The service is based in Leeds, West Yorkshire.

We rated this service as good because it was safe, caring, responsive, and well-led. We do not rate effective for this type of service...

Summary of findings

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Good 

Miracle Inside UK Ltd

Services we looked at:

Diagnostic imaging;

Summary of this inspection

Background to Miracle Inside UK Ltd

Miracle Inside UK Ltd is operated by Miracle Inside UK Ltd. The centre opened in April 2015 and provides diagnostic pregnancy ultrasound services to self-funding women, who are more than eight-weeks pregnant and aged 17 years and above.

All ultrasound scans performed at Miracle Inside UK Ltd are separate to those provided through the NHS. It is a private service in Leeds, Yorkshire, and primarily serves the communities of West Yorkshire. It also accepts service-user referrals from outside this area.

The service is registered with CQC to undertake the regulated activity of diagnostic and screening procedures. The service has had a registered manager in post since May 2015.

We have not previously inspected this service.

The service did not use or store any medications.

Our inspection team

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

Information about Miracle Inside UK Ltd

The service provided a diagnostic imaging service (ultrasound scans) to self-funding, pregnant women across West Yorkshire.

Miracle Inside UK limited offered the following services:

- Viability scans from eight to 10+6 weeks gestation.
- Dating scans from eight to 13 weeks.
- Reassurance scans from 13 to 34+6 weeks.
- Premium gender scans 15+2 to 34 weeks.
- 4D baby scans from 24 to 34 weeks.
- Position and presentation scans 34 weeks to birth.
- Non-invasive prenatal testing (NIPT).

All women accessing the service self-referred to the clinic and were private (self-funding) service users.

During the inspection, we visited the registered location in Leeds. We spoke with four staff: the registered manager, sonographer, studio assistant, and office manager.

We spoke with four women and their partners and relatives and observed four ultrasound scans.

There were no special reviews or investigations of the service ongoing by the CQC at any time during the twelve months before this inspection. This was the first inspection since registration with CQC in 2015.

Track record on safety for the period March 2018 to April 2019:

- No clinical incidents.
- No serious injuries.
- No formal complaints.

Services provided under service level agreements:

- Clinical and or non-clinical waste removal.
- Interpreting services.
- Maintenance of medical equipment.
- Maintenance of fire extinguishers and smoke alarms.

Summary of this inspection

The five questions we ask about services and what we found

We always ask the following five questions of services.

Are services safe?

We rated safe as **Good** because:

- The service provided mandatory training in key skills to all staff and made sure everyone completed it.
- Staff had training on how to recognise and report abuse, and they knew how to apply it.
- We observed well-presented staff who kept the equipment and premises clean.
- Staff kept clear records and completed and updated risk assessments for each woman through individual follow-up referral forms.
- The service had enough staff with the right qualifications, skills, training, and experience to keep people safe from avoidable harm and to provide the right care and treatment.
- Staff kept detailed records of women's appointments and referrals to NHS services and completed scan consent documents.
- The service had appropriate processes for staff to raise concerns and report incidents.
- Staff understood their roles and responsibilities to raise concerns and record safety incidents.

However:

- The service did not control all infection risks effectively.

Good



Are services effective?

We do not rate effective for this type of service. We found the following areas of good practice:

- The service provided care and treatment based on national guidance, and there was evidence of its effectiveness.
- Staff ensured women were comfortable, relaxed, and reassured during ultrasound scans.
- The service made sure staff were competent for their roles.
- Managers appraised staff's work performance, and there were processes to assess sonographers' competencies and suitability for their roles.
- Staff worked together as a team to benefit women and their families.
- Staff provided women with information regarding the scan findings and health promotion information regarding their pregnancies.

Summary of this inspection

- Staff understood how and when to assess whether a woman had the capacity to make decisions about their care.

However:

- Managers did not provide evidence that they monitored the effectiveness of care and treatment and used the findings to make improvements.
- Managers did not provide evidence that they evaluated images to ensure they were of good quality.

Are services caring?

We rated caring as **Good** because:

- Staff cared for women and their families with compassion. Feedback from women and their partners confirmed that staff treated them well and with kindness.
- Staff provided emotional support to service users to minimise stress.
- Staff involved women and those close to them in decisions about their care and treatment.

Good



Are services responsive?

We rated responsive as **Good** because:

- The service planned and provided services in a way that met the range of needs of people accessing the clinic.
- Women accessed the service and appointments in a way and at a time that suited them. There were no waiting times for appointments, and women self-referred to the service.
- The service had a complaints policy and treated concerns and complaints seriously. The registered manager investigated complaints and shared outcomes with all staff.

Good



Are services well-led?

We rated well-led as **Good** because:

- Managers had the right skills and abilities to run a service providing high-quality sustainable care.
- The service had a vision for what it wanted to achieve and plans to turn it into action.
- Managers across the service promoted a positive culture that supported and valued staff.
- The service engaged well with women, their partners, and local organisations to plan and manage appropriate services.
- The service was committed to improving, by learning from when things went well or wrong, and to promoting training.

However:

Good



Summary of this inspection

- The service did not have good systems to identify risks or to plan to eliminate or reduce them.
- The service had not completed a risk register and did not evidence any management of risks.
- The service did not provide evidence that it had collected, analysed, managed, and used information well to support all its activities.
- Some policies and procedures were not dated and were not specific to this organisation.

Detailed findings from this inspection

Overview of ratings

Our ratings for this location are:

	Safe	Effective	Caring	Responsive	Well-led	Overall
Diagnostic imaging	Good	Not rated	Good	Good	Good	Good
Overall	Good	N/A	Good	Good	Good	Good

Diagnostic imaging

Safe	Good 
Effective	Not sufficient evidence to rate 
Caring	Good 
Responsive	Good 
Well-led	Good 

Are diagnostic imaging services safe?

Good 

We rated safe as **good**.

Mandatory training

The service provided mandatory training in key skills to all staff and made sure everyone completed it.

- All staff members were required to undergo mandatory and statutory training relevant to their roles. All staff we spoke with had completed mandatory training; records were kept in individual staff files. Staff we spoke with said their mandatory training was easily accessible both online and face-to-face when necessary. The registered manager oversaw mandatory training requirements and allocated time for staff to complete it.
- Modules included equality and diversity awareness, health and safety at work, control of substances hazardous to health (COSHH), fire safety awareness, infection control, information governance, manual handling, basic life support, safeguarding vulnerable adults, safeguarding children levels 1 and 2, conflict management, and mental capacity act/deprivation of liberty safeguards.
- The compliance target for these modules was 100% for all staff with the exceptions of infection control (50%), manual handling (50%), and resuscitation (20%).

- We saw there was a specific requirement for all sonographers to evidence completion. This also applied to safeguarding training and training in awareness of female genital mutilation (FGM).
- All agency staff were required to provide a list of training records and competencies and to complete a job-specific competency checklist within three months, with assistance from a named mentor. We saw that all agency staff had complied with this requirement.

Safeguarding

Staff understood how to protect people from abuse and the service worked well with other agencies to do so

- Staff had full access to the service's Safeguarding Adults Policy and Procedures (April 2016) and Safeguarding Children Policy and Procedures (undated). Safeguarding training was part of the service's mandatory training programme. Staff described the escalation process to use if they were to have safeguarding concerns and were aware of the policies and where to find them. We were assured that staff had had training on how to recognise and report abuse and that they knew how to apply it.
- The safeguarding training for the sonographer included awareness of female genital mutilation (FGM). FGM is defined as the partial or total removal of the female external genitalia for non-medical reasons.
- Staff demonstrated a good knowledge of their roles with regard to protecting service users from harm or

Diagnostic imaging

abuse and reporting any issues. This included identifying risks to the service user's family, such as children and vulnerable adults whose main carers may be service users.

- Staff were clear about who the safeguarding leads were and how to escalate their concerns in line with the safeguarding policy. There were no safeguarding concerns reported to CQC in the twelve months prior to this inspection.

Cleanliness, infection control and hygiene

The service controlled most infection risk well

- The service had an infection control team, infection control lead, and decontamination policy (undated). Their role was to ensure the risk of infection to service users, visitors, and staff was minimised through a range of prevention and control processes. The infection control team monitored infection rates and audits to maintain standards.
- Housekeeping staff conducted regular cleaning of the scanning room. The ultrasound room was visibly clean, and we saw that there was a daily cleaning schedule. However, we saw that the room used to take bloods was carpeted, which could lead to an infection control risk. We raised this with the registered manager during the inspection, and he undertook to address this straight away.
- The ultrasound machine was cleaned by the sonographer for safety reasons. This was done between each usage, and there were records showing that deep-cleaning was undertaken at the end of each day.
- The registered manager conducted weekly spot checks to ensure compliance with service procedures. Checklists recorded whether the probe, cable, and ultrasound machine had been sanitised, as well as confirming the examination bed's padding, pillow, and paper had been replaced.
- We observed well-presented staff who kept equipment and premises visibly clean. They used control measures to prevent the spread of infection. Most infection risks were minimised, and in the preceding 12 months there had been no incidences of healthcare-acquired infections.

- During the inspection we saw that staff complied with good infection-control practice, such as wearing clean uniforms, being bare below the elbows, and having long hair tied up.
- There were effective systems for segregation and disposal of waste materials that reflected national guidance. The service had an agreement with a clinical waste removal company to remove clinical waste.
- There were alcohol hand-gel dispensers available for use in all clinical areas, and we saw staff using these appropriately.
- We saw the sonographer decontaminating her hands with gel before and after providing care and complying with the World Health Organisation's (WHO) 'Five Moments for Hand Hygiene'. These guidelines are for all staff working in healthcare environments and define the key moments when staff should be performing hand hygiene procedures to reduce risk of cross-contamination between service users.

Environment and equipment

The service had suitable premises and equipment and looked after them well

- The service was located on the ground floor of a fully-serviced business centre in Leeds, with two toilet facilities (including an accessible toilet and baby-changing facilities) situated adjacent to the scan room, service-user waiting area, scan studio, and reception.
- The scan room, service-user waiting area, scan studio, and reception were separate spaces with secure doors to maintain privacy and dignity. Arrangements were in place to safely and privately move service users from one area to another. Separate rooms were available to counsel and share bad news with service users, ensuring privacy.
- There was ample space in the scan room for the service user, sonographer, assistant, and equipment. The room contained a scan couch, chairs, a sofa, and a privacy screen. Bariatric equipment was available.
- Fire extinguishers were accessible and stored appropriately, and their maintenance schedules were up-to-date.

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- Cleaning products stored by the service were locked in cupboards in line with the Control of Substances Hazardous to Health Regulations 2002 (COSHH).
- We saw that ultrasound scanning machines had been tested for electrical safety, and parts had been replaced upon advice from the manufacturer. All servicing of the electrical equipment was completed by an external company, and staff were aware of when further services were due. We reviewed service records for the equipment, which detailed the maintenance history and six-monthly major services.
- Staff completed daily quality assurance checks of the ultrasound machine to ensure the equipment was safe to operate. We saw that staff had made regular checks on the quality of the equipment to ensure that image results recorded were accurate. For example, a probe had been replaced to ensure the equipment was safe for use.

Assessing and responding to service user risk

Staff completed and updated risk assessments for each woman through individual referral forms

- Upon booking an appointment, the service asked women to bring their pregnancy records, if available. Sonographers had access to obstetric and medical history records and could raise any concerns with the relevant medical practitioner and GP.
- The sonographer used the British Medical Ultrasound Society (BMUS) and Society and College of Radiographers (SCoR) systems ('Pause and Check') to reduce the risk of referrer error. Checks were carried out to correctly identify the service user and to confirm the site and/or side to be imaged, identify the existence of previous imaging, and ensure that the correct imaging modality was used. The sonographer checked the service user's identity, and the procedure was fully explained to service users.
- Staff described to us action they would take if a service user were to become unwell or distressed while waiting for, or during, an ultrasound scan. The action to be taken depended on the specific situation, and staff were able to provide appropriate examples.
- The service had processes for the management of any service user who might suddenly become unwell

whilst on the premises. In the event of a cardiac arrest, staff would call 999 for an ambulance. The service confirmed there had been no incidences requiring an ambulance.

- Staff were trained in basic life support, and the registered manager had attended cardio-pulmonary resuscitation (CPR) training and had the skills to resuscitate service users in the event of an emergency.
- There were clear processes and pathways in place to guide staff on what actions to take if the sonographer identified unexpected results on the scan. When asked, staff were clear about what these actions were, and they gave us an example involving a referral to the local NHS trust within the preceding 12 months. Staff documented referrals on dedicated 'further action referral' forms, which were reviewed for completeness by the registered manager.
- All staff undertaking procedures were aware of situations in which examinations may be contraindicated. They were also aware of nationally recommended mechanical and thermal indices and the 'as low as reasonably achievable' (ALARA) principle for selecting dosage.
- Staff advised women about the importance of attending their NHS scans and appointments in addition to this service. The sonographers made sure that service users understood that the ultrasound scans that they performed were additional to the routine care they should receive as part of their NHS maternity pathway.

Staffing

The service had enough staff with the right qualifications, skills, training and experience to keep people safe from avoidable harm and to provide the right care and treatment

- The service operated five days per week, with appointments available from 10.30 to 13.30 on Mondays, in the afternoons on Wednesdays, Thursdays, and Fridays, and from 09.00 to 19.00 on Saturdays. Around 20 to 22 service users were seen each day.

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- The registered manager ensured the scan centre operated safely and effectively. He used the World Health Organisation's Workload Indicators of Staffing Need (WISN) tool to determine the numbers of each type of health worker the service required.
- The centre was staffed by one sonographer, one front-office manager, and one studio assistant each day.
- There were no national guidelines for staffing of an ultrasound scan centre, and the registered manager and sonographer were the only full-time employees for the service. The registered manager and the sonographer both worked four days per week.
- Two further staff were employed as front office managers, and two more were studio assistants. These members of staff both worked two days per week for 15 hours, ensuring the service was fully-staffed.
- The service did not employ medical staff. Two consultant radiologists were contracted to review images and any issues raised as required and to undertake audits of scans and peer reviews of both image quality and reporting.
- Two locum sonographers and three locum administrative staff were contracted for the provision of sickness and holiday cover.
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The service's sickness rate for the preceding 12 months was 10% for front-office managers and 5% for studio assistants.

Records

Staff kept detailed records of women's appointments, referrals to the NHS services and completed scan consent documents

- The service had a records management policy (December 2018), which detailed processes for ensuring the completion, use, tracking, storage, retrieval, archiving, and disposal of clinical records, irrespective of format.

- The service did not have access to service users' medical records, with the exception of maternity notes checked by the sonographer to verify the service user's details (name, age, previous scans, practitioner notifications) before scans were undertaken.
- We saw that records were clear, up-to-date, and easily available to authorised staff. Staff recorded information in a clear and accurate way, including the estimated due-date, the type of ultrasound scan performed, findings, conclusions and recommendations, and consent.
- Service user records were stored on a database and securely managed to keep service users safe and prevent confidential and sensitive information from being shared incorrectly. The sonographer used paper documentation to record outcomes; these were signed and recorded her Health and Care Professions Council (HCPC) registration.
- All service users who used the service were self-referred or referred by midwives or GPs. All outcomes and medical notes were given to the service user, who could then decide whether to share the information with her medical practitioner.
- We saw that service users' files and consent forms were kept in locked units, and keys were stored in a secure place accessible only to authorised staff. Service user records were held for five years, and the service had a process for the destruction and disposal of paper records.

Medicines

- The service did not store or administer any medicines.

Incidents

The service had appropriate processes for staff to raise concerns and report incidents. Staff understood their roles and responsibilities to raise concerns and record safety incidents

- The service had an incident reporting policy (dated January 2019). This policy covered the reporting and investigation of incidents, together with processes for analysis and improvement.
- The service aimed to establish the causes of incidents, complaints, and claims, to understand these, and to

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ensure lessons were learnt and improvements made to avoid recurrence. The policy confirmed the safety and reporting culture within the service and detailed effective management of adverse incidents, including near misses, ill health, and hazards.

- The policy sought to ensure that all incidents, whether or not they had caused actual harm, were reported by staff in a timely manner. The policy also included guidance and reporting requirements to regulatory bodies. The service had not reported any incidents in the 12 months prior to the inspection.
- The registered manager was responsible for investigations into all incidents. Staff we spoke with knew how to report incidents and could give examples of when they would do this.
- The service had not had any cause to use emergency services to transfer service users to an acute trust or another healthcare provider within the 12 months prior to the inspection.
- The service had a process enabling the sonographer to discuss results of an ultrasound with relevant healthcare professionals (with the service user's consent) via telephone, if findings which required escalation were to be identified. This would be followed up with a formal 'further action report' to be taken by the service user to their medical practitioner.
- Duty of candour is a regulatory duty that relates to openness and transparency and requires providers of health and social care services to notify service users (or other relevant persons) of certain 'notifiable safety incidents' and provide reasonable support to that person. Staff were aware of this duty and the need to be open and honest with service users should such an incident occur. The service had not needed to do this in the 12 months prior to inspection.

Are diagnostic imaging services effective?

Not sufficient evidence to rate 

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We do not rate effective for this core service.

Evidence-based care and treatment

The service provided care and treatment based on national guidance and evidence of its effectiveness

- We saw that the service complied with national guidelines from the Health and Care Professions Council (HCPC), National Midwifery Council (NMC), the British Medical Ultrasound Society (BMUS), and the Society and College of Radiographers (SCoR) and followed national guidelines developed by the National Institute for Health and Care Excellence (NICE).
- All sonographers were members of the British Medical Ultrasound Society (BMUS) and the Society and College of Radiographers (SCoR) and held professional indemnity insurance. Sonographers followed SCoR's 'Making the best use of an imaging department' guidance on current scanning protocols.
- Sonographers followed SCoR's standards and code of conduct, which set out required standards of conduct and ethics, as well as other principles for safe and effective practice by sonographers. The code of conduct provides a framework for assessing the conduct and ethics of sonographers for the purposes of membership of the college and other recognised bodies.
- Standard operating policies and procedures were available to all staff, and they knew where to access guidance and policies if they were to need any clarification. The service had formal agreements with two consultant radiologists to review images or issues raised as required and to carry out peer review of image qualities and reporting.
- Sonographers followed NICE's 'Ectopic Pregnancy and Miscarriage: diagnosis and initial management' guidance (NICE, 2012), and protocols were in place for the referral of women to the local NHS trust when necessary.
- Written consent was obtained from all service users, following completion of a pre-scan questionnaire and discussion with the sonographer.
- The service had a policy and procedure (undated) for internal audit and an audit and assurance operational

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plan for 2019. However, when we requested sight of completed audits, including those scheduled for completion by the end of February 2019, the service did not provide us with any of these.

Nutrition and hydration

The service did not offer food to women

- A water dispenser and a hot drinks machine were available for service users and visitors in the waiting area.
- Staff gave women appropriate information about drinking water before a scan, to ensure they attended with a full bladder to enable the sonographer to gain a clear scan image.

Pain relief

- Staff did not formally monitor pain levels as the procedure was pain-free. However, we witnessed staff asking women whether they were comfortable during their scan.

Service user outcomes

Staff reported that they monitored the effectiveness of care and treatment and used the findings to improve them

- The service had scheduled regular audits to monitor performance and to maintain standards. However, the service did not respond to our request for sight of any audits that had been carried out.
- The service had formal agreements with two consultant radiologists to review images and issues raised as required, to carry out peer reviews, and to audit image quality and reporting.
- The service benchmarked itself against other similar providers in respect of number of reviews received, number of rescans, and number of completed scans.
- The service monitored service user outcomes and experience through service user satisfaction feedback received on site and online.
- Although the management board held five meetings each year, minutes (May 2018 and November 2018) did not show any discussion by the board of compliance

with audits related to service user outcomes. It did not appear that any service-user outcomes, such as accuracy rate for gender confirmation scans, for example, were monitored by the management board.

Competent staff

The service made sure staff were competent for their roles.

- Managers appraised staff's work performance and there were processes in place to assess sonographer competencies and suitability for their role.
- The service employed staff in compliance with its recruitment, selection, and staffing levels policy and procedure (December 2016), which clarified the processes to be followed for all recruitment and selection from securing approval to recruit, through advertising a post and short-listing candidates, to selecting and appointing.
- All staff had the right qualifications, skills, knowledge, and experience to do their jobs at the time of appointment, when they took on new responsibilities, and on a continuous basis.
- In particular, sonographers complied with standards of behaviour in relation to the code of conduct of sonographers, annual confirmation of professional registration, continuous professional development (CPD), and appraisals.
- The registered manager had appraised 100% of sonographers and 50% of front office managers eligible for an appraisal within the preceding 12 months, in line with the service's appraisal policy (March 2018).
- We saw that the sonographer held relevant ultrasound qualifications approved by the Consortium for the Accreditation of Sonographic Education, was registered with the Health and Care Professions Council (HCPC), and was also a member of the British Medical Ultrasound Society (BMUS) and the Society and College of Radiographers (SCoR). The sonographer held professional indemnity insurance. She attended annual conferences and undertook continuous professional development, supervision, and appraisal.

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- The service had made formal agreements with two consultant radiologists to review images or any issues raised, to peer review image quality and reporting, and to review retraining and professional development. The process was due to begin in May 2019, with peer review of scans planned at six-monthly intervals.
- Staff records contained references, disclosure and barring service checks, written statements of terms and conditions of employment, and proof of qualifications. The sonographers had been issued with statements of terms and conditions of employment which identified their responsibilities and standards of behaviour in relation to the code of conduct of sonographers, annual confirmation of professional registration, continuous professional development (CPD), and appraisals.
- The appraisal process (March 2018) was designed to maximise the effectiveness and potential of each member of staff. Additional training requirements were identified during appraisals, and external training was funded by the service.
- The registered manager appraised individual work performance and had introduced supervision meetings to provide additional support and monitor the effectiveness of the service.

Multidisciplinary working

Staff of different kinds worked together as a team to benefit women and their families.

- During the inspection we saw that the team worked well together and observed positive communication between the sonographer and support and administrative staff.
- The service ensured that, when a woman had given consent for her information to be shared, medical practitioners received a copy of her ultrasound report.
- A genetics counsellor was available to provide specific advice and counselling when needed.

Seven-day services

- The service operated five days per week, between the hours of 10.30 and 13.30 on Mondays, on Wednesday, Thursday and Friday afternoons, and between 09.00

and 17.00 on Saturdays. Clinic sessions were designed to accommodate the needs of women and their families, with appointment times set to enable working mothers and siblings-to-be to attend.

- Approximately 20 to 22 service users were seen each working day.
- The centre was staffed by one sonographer, one front-office manager, and one studio assistant each day.
- Women could book appointments online or by telephone, at a time to suit them.

Health promotion

- The service provided a wide range of leaflets about pregnancy-specific issues (e.g. morning sickness, complications in pregnancy) and other information for mothers-to-be.

Consent and Mental Capacity Act

Staff understood how and when to assess whether a woman had the capacity to make decisions about their care.

- As part of their mandatory training staff had completed training in the Mental Capacity Act (2005) and deprivation of liberty safeguards.
- Although staff had never been asked to scan a woman who could not give consent, they were able to describe the service guidelines and process for dealing with such a situation.
- All women received written information before their scan. This included a technology and safety briefing, terms and conditions, and information about scan limitations, medical records, consent, and use of data.
- The pre-scan questionnaire and declaration form included a declaration that the woman was receiving appropriate pregnancy care and consent to share information, if necessary.
- All staff were aware of the importance of gaining consent from women before conducting a scan. The sonographer confirmed the woman's identity and details prior to the scan and obtained verbal consent to begin.

Diagnostic imaging

Are diagnostic imaging services caring?

Good 

We rated caring as **good**.

Compassionate care

Staff cared for women and their families with compassion

- The service policy on privacy, dignity, and respect (December 2018) had been developed to ensure all service users always had their rights acknowledged and encouraged staff to promote these.
- We saw staff treated service users with kindness, dignity, and respect. We observed staff providing calm, clear guidance and checking how service users were feeling and that they were happy with any explanations during and after their scans.
- The sonographer told us she would subsequently contact midwives to enquire about the service user's wellbeing for those referred on to maternity services.
- We saw that all staff wore name badges, introduced themselves, and explained their roles to service users. Staff took time to interact with service users in a respectful and considerate manner. They showed an encouraging, sensitive, and supportive attitude to service users and those close to them.
- Staff understood and respected service user's personal, cultural, social, and religious needs, and they took these into account.
- The sonographer used sheets to cover service users' clothing to protect them from getting wet after the use of cold gel. Staff provided skin care by wiping off gel following procedures.
- The service sought feedback from service users with a comments book and via social media; we saw positive feedback in the comments book. Staff told us that service-user satisfaction was extremely important and described offering further free scans if a service user was disappointed with the image quality.
- The service conducted a service user satisfaction survey which showed that 80% of service users were

'extremely likely' to recommend the service. Following a scan, service users were escorted to the main reception area to choose their scan pictures and provided with all of the items included in their package. Service users were encouraged to complete the satisfaction survey or encouraged to write their feedback in the comments book.

- We were told that negative comments were not deleted from social media, as the service preferred to show that it addressed any feedback and wanted the public to have confidence that positive reviews were genuine.
- The registered manager told us that, although locum sonographers were available, the service had sometimes been closed when the regular sonographer was not available, because former service users had expressed a preference to be seen by her, and new service users had also requested her, having chosen the service by word-of-mouth and reputation.
- During the inspection we spoke with five service users; some were returning for further scans and said they had 'really enjoyed' their first scans. Other service users were returning to the service having been pleased with their experience there during previous pregnancies.

Emotional support

Staff provided emotional support to service users to minimise their distress

- Staff were trained to provide chaperone support if the service user requested it.
- If a scan identified anything of concern, the sonographer would discreetly alert the rest of the staff by walkie-talkie signal; all staff understood and could describe the signals used. The service had developed a procedure by which the office manager would attend the scan room following a signal to provide additional support to the service user, while the sonographer shared the scan findings with her.
- Staff told us that a deposit was taken at the time of booking the scan. If a service user had not already paid in full before attending for her scan and something of concern was found during the scan, she would not be asked to pay anything more.

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- The waiting area was set apart from the scan area so that a service user who had received bad news did not have to encounter anyone else who was waiting for a scan when leaving the premises.
- If a non-invasive prenatal test showed it was likely that the baby may have a genetic condition, the service arranged for a genetic counsellor to share the result with the service user. The counsellor would then signpost the service user to further emotional support and also help her to access a definitive diagnosis.

Understanding and involvement of service users and those close to them

Staff involved women and those close to them in decisions about their care and treatment

- Scans were tailored to meet the wishes of service users and their relatives. The sonographer asked service users whether they wanted to know the sex of the baby and avoided revealing it if necessary.
- When service users or their relatives were interested in a certain view of the baby, the sonographer focused the scan on getting the best possible images for them. For example, one service user particularly liked a view of her baby resting his head on his arm. The sonographer spent time getting the best angle and image clarity to produce the best quality image for the family to keep.
- The scanning process was relaxed, and the sonographer was happy to take questions from service users and their families, explaining about the baby's heart rate and fluid surrounding the baby, for example.
- Scan options and costs were clearly explained to prospective service users during initial enquiries. This information was also clearly displayed on the website and in leaflets and folders in the waiting area.
- The service had prepared information for prospective service users who were considering non-invasive prenatal testing (NIPT) to assess the likelihood that their baby may have a genetic condition. It was clearly explained that NIPTs were indicative, not diagnostic, and that service users would need further tests to confirm a diagnosis if the NIPT returned a positive result.

- All service users and family members we spoke with understood when and how they would receive their scan results. They were offered a variety of options to take images home, including photos, memory sticks, and CDs.
- The service offered a variety of 'gender reveal' options for purchase, including scratch cards, cakes with pink or blue fillings, and cannons with pink or blue confetti, to help service users share their news with family and friends.

Are diagnostic imaging services responsive?

Good 

We rated responsive as **good**.

Service delivery to meet the needs of local people

The service planned and provided services in a way that met the range of needs of people accessing the clinic

- The service had effective links with midwifery services in local NHS hospitals and could directly refer service users to ensure follow-up when necessary.
- Free parking was available, and the building was located near bus stops and road links.
- Appointments were regularly available, including some weekday evenings and all day on Saturdays. However, although the website stated that the service was open Monday to Saturday from 09.00 to 19.00, appointments were actually limited to between 10.30 and 13.30 on Mondays and were not available to book at all on Tuesdays or during mornings from Wednesday to Friday.
- The waiting area had comfortable seating, hot drinks were available for purchase, and water was available free of charge.
- To make viewing scans as easy as possible, the ultrasound monitor was placed directly in front of the service user and a large screen was sited directly in front of seating for family and friends.

Meeting people's individual needs

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The service took account of service users' individual needs, it had a proactive approach to understanding individual needs, was accessible and promoted equality

- Information about the scan packages available was displayed on the website and provided during telephone enquiries. Staff guided prospective service users to choose the right package for them, depending on the stage of their pregnancy and the additional features included in the package, such as high-definition scanning, extra photos and videos, or keepsakes such as keyrings or teddy bears.
- The premises were accessible for service users with a disability.
- The service did not have any arrangement with translation or interpreting services. There was no provision of information in any language other than English. However, managers told us that staff spoke a range of languages and were happy to interpret where possible.

Access and flow

Women could access the service and appointments in a way and at a time that suited them

- The service was open on Saturdays to meet demand.
- The service did not have a waiting list. Appointments were available during the week of booking.
- Appointments were allocated directly by the online booking system, and the service did not take bookings over the telephone to avoid double-booking or over-booking.

The service had a fixed number of appointments each day, and this was monitored through the online booking system. There were two different appointment slots: a 15-minute shorter scan; and longer appointments of 30 minutes for the more complex scan packages.
- No appointments had been delayed or cancelled due to non-clinical reasons, such as equipment breakdown or staff absence. When a service user did not attend their appointment, staff made contact and recorded this in their notes. Staff offered service users another appointment or refunded monies paid, if required.

- Service users told us they had found it easy to book an appointment which suited them, in a timely fashion.
- Appointments were planned and timed to allow sufficient time for the sonographer to complete a written report in time for the service user to take it away immediately.

Learning from complaints and concerns

The service had a complaints policy and treated concerns and complaints seriously. Complaints were investigated, and lessons learned from the results, and shared with all staff

- Service users we spoke with knew how they could make a complaint or raise concerns. We saw information displayed in all areas of the service, including the waiting area, office, and scan room, explaining how to make a complaint.
- The service had a complaints policy which had been reviewed in December 2018. The complaints management procedure aimed to identify and address concerns in a mutually satisfactory manner.
- Staff told us they had never received any formal complaints and aimed to resolve any concerns before they reached that stage. However, should a complaint be received, staff were confident learning would be shared during team meetings and changes be made to practice as necessary.
- Service users and those close to them were encouraged to raise any concerns or issues with staff or the person in charge in the first instance. Staff told us they were empowered to attempt to resolve concerns locally wherever possible.
- The service's social media sites provided a way for service users to provide informal feedback. Staff responded directly on social media and offered telephone calls where appropriate.

Are diagnostic imaging services well-led?

Good 

We rated well-led as **good**.

Leadership

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Managers at all levels in the service had the right skills and abilities to run a service providing high-quality, sustainable care

- The service's managing board described itself as committed to serving the interests of the company and achieving sustainable growth in company value. Members of the board were jointly responsible for the management of the company, business policy, and corporate strategy.
- The management structure consisted of directors, senior advisors, consulting advisors, and advanced ultrasound practitioners. The registered manager oversaw sonographers and studio assistants and was responsible for the everyday running of the service.
- The registered manager and the full-time sonographer were contactable to answer queries or for discussion about all services and procedures. The registered manager was fully aware of the scope and limitations of the service, based on the size, procedures offered, and numbers and type of staff.
- The registered manager had the skills, knowledge and experience needed to effectively manage the service. Staff told us managers were approachable, supportive, and effective and had the skills and knowledge to ensure service users received a quality service.
- We were told that the registered manager promoted a positive culture that supported and valued staff, creating a sense of common purpose based on shared values.
- The service operated a 'no blame' culture to encourage team-working, both within the service and with external organisations. There was a clear team culture with annual team bonding events and a focus on professional standards, continuous professional development, and appraisals.

Vision and strategy

The service had a vision for what it wanted to achieve and workable plans to turn it into action.

- The service had developed a business plan, which contained its objectives, details of the products and services available, a strengths and weaknesses analysis, and an ongoing strategy.

- The service vision included goals to '...maintain capacity, continue to ensure safety and the delivery of a high-quality service and to support physicians in the decision-making process for the care of their service users'.
- The service aimed to work more closely with the local NHS trust and engage with the local clinical commissioning group (CCG) to reduce excess demand on the ultrasound service across providers.

Culture

Managers across the service promoted a positive culture that supported and valued staff, creating a sense of common purpose based on shared values.

- Staff worked together well as a team, and there was an open culture. Those we spoke with said managers were '...open to ideas' and '...receptive to ideas.' Staff said it was a '...lovely job' and they were encouraged to promote best service-user service.
- We saw a 'no blame' approach to the investigation of complaints, and the registered manager addressed performance issues through one-to-one feedback with staff.
- All staff spoke positively about their roles within the service and told us that they felt valued and supported in their work by colleagues and the registered manager.
- There was a strong emphasis on care of service users and their families. Staff promoted openness and understood how to apply the duty of candour. Staff were aware of the meaning of the term 'duty of candour.'
- Throughout our inspection, the registered manager responded positively to feedback, suggesting willingness to learn and improve.

Governance

The service systematically improved service quality and safeguarded high standards of care by creating an environment for good clinical care to flourish.

- The management board held five ordinary meetings each year; extraordinary meetings were convened as

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required. Minutes (May 2018 and November 2018) showed the board had discussed procedures offered, bookings, holidays, health and safety, and working hours.

- The service's registered manager was its governance lead, supported by a clinical governance board. The board consisted of consultant radiologists, a registrar in gynaecology, a clinical speciality advisor, a medical physics advisor, a quality-monitoring advisor, a training co-ordinator, and human resources consultants.
- The service had a governance policy which outlined the responsibility of board members and the requirement for regular audits. A proposed audit and case review process had been developed. This identified the need for service improvement and a process of review and learning that contributed positively to sonographers' continuing professional development. Consultant radiologists planned to review the audit to maintain standards.
- The audit would identify whether the indication for the examination was appropriate, all information required had been recorded, and images had been made of all the structures that should have been examined. The audit would also confirm that images demonstrating abnormalities were reported, all regions that should have been examined were covered, and Doppler and dynamic examination had been used appropriately and recorded.
- The service audit committee comprised one independent member of the board. Based on their education and professional experience, all members of the committee appeared to have sufficient knowledge of finance and accounting.
- The service had indemnity and medical liability insurance which covered all staff working within the service for the case of a legal claim and was in date until October 2019.
- The service had robust recruitment processes in place, which included references and Disclosure and Barring Service (DBS) checks. There were procedures to ensure staff members' fitness to work with vulnerable adults, and the service confirmed that essential checks had been carried out for all staff.

- There were appropriate policies and procedures for the operation of the service, and these were up-to-date, compliant with review dates, and available to staff. However, some policies and procedures had been adapted from those of other organisations and still referred to the originating service (e.g. an NHS trust).

Managing risks, issues and performance

The service had limited systems to identify risks, plan to eliminate or reduce them, and cope with both the expected and unexpected.

- The service had procedures for risk assessment and management (undated) and standard operating procedures (undated). These defined the types of risk that could arise within the service and the responsibilities of managers to identify, manage, and review those risks.
- The service did not provide a specific, up-to-date risk register except for those risks identified within the scope of the control of substances hazardous to health (COSHH) regulations 2002. The corporate risk register identified generic risks, not those currently identified.
- The service had a critical incident planning policy (undated), policy on reporting adverse incidents (undated), and a business continuity framework (September 2018) which identified and mitigated risks and disruptions that could affect the capability of the service to continue to deliver its activities during a disruptive incident.
- There was no evidence that the service undertook any drills to ensure that staff were aware of the process to take in the event of an emergency.

Managing information

The service collected, analysed, managed and used information well to support all its activities, using secure electronic systems with security safeguards.

- The service's records management policy detailed processes for the effective governance of information and established a framework which ensured that all information was dealt with legally, securely, and efficiently. The service had a Caldicott guardian, who was responsible for overseeing access to and the sharing of service-user-identifiable information.

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- The registered manager was responsible for ensuring that practical guidance and advice on the management, retention, and disposal of records was available and that requests for access to healthcare records were managed appropriately.
- All staff had responsibility for the maintenance, management, and care of clinical records in accordance with the service's policy, as part of their own accountability for governance.
- Responsibility extended to maintaining the appearance, tidiness, and integrity of the record and also the safe custody of records in their possession. Where health records were in clinical use outside designated areas, they were held securely. Where rooms containing health records were unattended, we saw that they were locked.
- Service users gave consent for the service to store their records as part of their signed agreement detailing the procedure. This demonstrated compliance with the General Data Protection Regulation (GDPR) 2018.
- We saw that feedback about the procedures, sonographer and staff had been overwhelmingly positive. Responses showed the service was viewed as flexible and reliable with professional and dedicated staff.
- Suggestions had been received on setting up a patient-participation group to meet, exchange ideas, and use information from service users to improve the running of the service and introduce new services, thus involving them in service delivery.
- Service user feedback was used in the 360-degree appraisal process of the lead sonographer to identify any issues or potential improvements, and feedback and actions for improvement were shared at team meetings.
- All service users we spoke with told us they would recommend the service to others and would not use any other provider.
- We observed effective manager engagement with staff. All staff we spoke with told us that managers were supportive, accessible, and visible.

Engagement

The service engaged well with women, their partners, and local organisations to plan and manage appropriate services, and collaborated with partner organisations effectively.

- The service asked service users to complete a satisfaction survey. There were also opportunities for women and their partners to leave comments on social media pages and online review sites. The service enabled service users to comment by providing feedback and suggestions on the quality of service received during their ultrasound examination.

Learning, continuous improvement and innovation

The service was committed to improving services by learning from when things went well or wrong and promoting training.

- The service had recognised the importance of the security of patient-identifiable data management systems and processes. It had collaborated with an international information management company to design and develop its ultrasound data-management reporting system for the transfer of images and reports to service users.

Outstanding practice and areas for improvement

Areas for improvement

Action the provider SHOULD take to improve

- The service should ensure that all infection risks are controlled effectively.
- Managers should ensure they monitor the effectiveness of care and treatment and use their findings to make improvements.
- Managers should ensure they evaluate images to ensure they are of good quality.
- The service should set up and use systems to identify and plan to eliminate or reduce risks.
- The service should ensure a completed risk register is used to manage identified risks.
- The service should ensure evidence collected is analysed and used to support all activities.
- The service should ensure policies and procedures are specific to the provider.