Miracle in Progress

Quality Report

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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

Summary of findings

Letter from the Chief Inspector of Hospitals

Miracle in Progress is operated by Miracle in Progress Ltd. The service is a fixed location private clinic providing obstetric ultrasound, screening blood tests and gynaecological services for women aged over 17 years across Leicestershire.

We inspected this service using our comprehensive inspection methodology. We carried out a short-notice announced visit to the service on 11 October 2019.

To get to the heart of patients' 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.

Services we rate

Our rating of this service improved. We rated it as **Good** overall.

We found the following areas of good practice:

- The service now provided mandatory training in key skills to all staff and made sure everyone completed it.
- Staff now understood how to protect people from abuse and had completed safeguarding training on how to recognise and report abuse. Staff knew how to apply this training.
- The service controlled infection risk well. Staff used equipment and control measures to protect patients, themselves and others from infection. They kept equipment and the premises visibly clean.
- The service managed patient safety incidents well. Staff recognised and reported incidents and near misses. Managers investigated incidents and shared lessons learned with the whole team and the wider service. When things went wrong, staff apologised and gave patients honest information and suitable support. Managers ensured that actions from patient safety alerts were implemented and monitored.
- The provider mostly had appropriate arrangements in place to assess and manage risks to women.
- 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 made sure staff were competent for their roles. Managers appraised staff's work performance.
- Staff worked together as a team to care for the women and those who accompanied them.
- Services were available six days a week.
- Staff cared for women and their families with compassion. Feedback from women confirmed that staff treated them well and with kindness.
- The service planned and provided services in a way that met the range of needs of people accessing the service.
- Women could access the service when required.
- The service was inclusive and took account of patients' individual needs and preferences. Staff made reasonable adjustments to help patients access services. They coordinated care with other services and providers.
- Managers in the service had the right skills and abilities to run a service providing high-quality sustainable care.
- Staff at all levels were clear about their roles and accountabilities and had regular opportunities to meet, discuss and learn from the performance of the service.

Summary of findings

- The provider had a vision for what it wanted to achieve, and staff could articulate this. workable plans to turn it into action, which it developed with staff, women and local community groups.
- Managers across the service promoted a positive culture that supported and valued staff, creating a sense of common purpose based on shared values.

However:

- The service did not monitor all aspects of effectiveness of care and treatment. The service did not complete audits into the quality of the scans provided or take part in a peer review process.
- The provider had not completed all risk assessments required.
- The provider did not have standardised document controls for policies with issue and review dates identified.
- The provider did not have an up-to-date website, to reflect the service provided.

Heidi Smoult

Deputy Chief Inspector of Hospitals (Central Region)

Summary of findings

Our judgements about each of the main services

Service	Rating	Summary of each main service
Diagnostic imaging	Good 	Miracle in Progress provided ultrasound scanning services, which was classified under the diagnostic core service. We rated this service as good overall because mitigating actions had been taken to address issues identified during our last inspection in April 2019.

Summary of findings

Contents

Good

Miracle in Progress

Services we looked at
Diagnostic imaging

Summary of this inspection

Background to Miracle in Progress

The Leicestershire clinic opened in 2010 and primarily serves the communities of the Leicestershire region, though it also accepts women from outside this area.

The service provided baby scans including early pregnancy scans, well-being checks, growth and presentation scans and 4D scans including keep sakes and souvenirs.

The service has had a registered manager in post since 2013. We previously inspected this service on 6 April 2019 using our focused methodology and inspected the safe and well led domains.

During the inspection on 6 April 2019 the provider was issued with a Section 31 urgent suspension of registration for a period of six weeks, in relation the identified six breaches of regulated activity. The breaches of regulation included:

- Regulation 12 HSCA 2008 (Regulated Activities) Regulations 2014 Safe care and treatment.
- Regulation 13 HSCA 2008 (Regulated Activities) Regulations 2014 Safeguarding service users from abuse and improper treatment.
- Regulation 17 HSCA 2008 (Regulated Activities) Regulations 2014 Good governance.
- Regulation 18 HSCA 2008 (Regulated Activities) Regulations 2014 Staffing.
- Regulation 19 HSCA 2008 (Regulated Activities) Regulations 2014 Fit and proper persons employed.
- Regulation 20 HSCA 2008 (Regulated Activities) Regulations 2014 Duty of candour.

The provider requested a follow up inspection two weeks after the temporary suspension had been implemented. During the follow up inspection we saw evidence that the service had improved, with new processes introduced to ensure safe care. The temporary suspension of registration was lifted following this visit.

Our inspection team

The team that inspected the service comprised of two CQC Inspectors and was overseen by an inspection manager.

Why we carried out this inspection

We carried out this inspection as part of our schedule inspection programme.

How we carried out this inspection

We carried out this inspection using the CQC comprehensive approach.

Summary of this inspection

Information about Miracle in Progress

The service was located on the ground floor of a retail unit and was fully accessible. The service had two scan rooms, a reception and waiting room. The service was registered to provide the following regulated activities:

- Diagnostic and screening procedures
- Maternity and midwifery service

At the time of our inspection the service was not delivering any maternity and midwifery services so we were unable to inspect the core service.

All women accessing the service self-referred to the service and could book an appointment at a time to suit them. The service closed on a Wednesday and opened six days a week and included evening appointments.

At the time of our inspection the service consisted of the owner who was also the registered manager and the sonographer, a clinic manager, two receptionists and a self-employed sonographer, who was called in to cover annual leave or if the demand was high. The service did not employ any medical staff. The service did not use or administer any medicines.

During the inspection, we visited all clinical areas. We spoke with three staff including the registered manager, the clinic manager and a receptionist. We spoke with three women and two relatives. We also reviewed 10 policies and procedures, referral forms, scan reports and three sets of women's records from the well-being and gender scan service.

The service had been subject to a temporary suspension order following our inspection in April 2019, this was removed in May 2019.

Activity (April to September 2019):

- In the reporting period from April to September 2019 there were 1,737 scans recorded at the service.
- In the reporting period from April to September 2019 there were 133 appointments that women had booked and did not attend.

Track record on safety (reporting period April to September 2019):

- The service had no serious incidents.
- The service had no never events.
- The service received five complaints between April to September 2019.

Services provided under service level agreement:

- Collection of clinical waste.
- Laboratory for analysing blood tests.
- Cleaning service.

Detailed findings from this inspection

Overview of ratings

Our ratings for this location are:

	Safe	Effective	Caring	Responsive	Well-led	Overall
Diagnostic imaging	Good	N/A	Good	Good	Good	Good
Overall	Good	N/A	Good	Good	Good	Good

Good

Diagnostic imaging

Safe	Good
Effective	
Caring	Good
Responsive	Good
Well-led	Good

Are diagnostic imaging services safe?

Good

Our rating of safe improved. We rated it as **good.**

Mandatory training

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

Staff received and kept up-to-date with their mandatory training. This had improved since our last inspection where the provider had not ensured staff received mandatory training in key skills and kept up-to-date with their training. Staff we spoke with confirmed they had completed their mandatory training. This was confirmed following review of staff files.

The mandatory training was comprehensive and met the needs of patients and staff. It included safeguarding, infection prevention and control, chaperone training, health and safety, manual handling, equality and diversity and Prevent training. Prevent training aims to safeguard vulnerable people from being radicalised to supporting terrorism or becoming terrorists themselves.

The mandatory training was comprehensive and met the needs of patients and staff. All staff received an induction when first employed by the service. We saw induction checklists in staff files which included all required subject areas. Staff told us they had a period of job shadowing when they first started to learn the requirements of their role.

All staff completed training on recognising and responding to patients with mental health needs, learning disabilities and autism. The service had an equality and diversity policy which was issued in June 2019. The policy included information related to discrimination and referenced the Equality Act 2010. The policy included reference to patients with mental health issues, autism and learning difficulties.

Managers monitored mandatory training and alerted staff when they needed to update their training. Mandatory training information and completion data were held on an electronic system. The system was available on a mobile phone app which all staff could access. The level of access each member of staff had was dependent on their role. All staff could access their own records and the managers could access all records. The managers received an alert a month before mandatory training was due for each member of staff, they would then book the appropriate training.

Safeguarding

Staff understood how to protect patients from abuse and the service worked well with other agencies to do so. Staff had training on how to recognise and report abuse, and they knew how to apply it.

Staff received training specific for their role on how to recognise and report abuse. This was an improvement since our last inspection. The training was in line with the safeguarding children and young people roles and competences for health care staff intercollegiate document 2014. The registered manager was the identified safeguarding lead and had completed level three safeguarding training for both children and adults. All other staff were trained to level two as a minimum.

Safeguarding training included awareness of child sexual exploitation, female genital mutilation and modern slavery. Information about modern slavery was displayed on the office information board, staff we spoke with were aware of this.

Staff knew how to identify adults and children at risk of, or suffering, significant harm and worked with other agencies to protect them. Staff we spoke with could identify an adult or child who was at risk of or suffering, significant harm. They showed a good awareness of child sexual and female genital mutilation and modern slavery.

Staff knew how to make a safeguarding referral and who to inform if they had concerns. The service had flow-charts and the NHS Safeguarding Midlands and East Guide on display in the office of actions to take if staff needed to report to the local authority. All staff we spoke with knew where this information was and their responsibility to report concerns.

The service had a recruitment and selection policy issued in May 2019. The provider required all staff to have an enhanced disclosure and baring service (DBS) check as part of the recruitment policy. We saw all staff had a DBS check at the time of our inspection.

All staff in the service had undergone level two chaperone training, which included training on the role and responsibilities of a chaperone, confidentiality and how to raise concerns. A chaperone policy was in place and had been updated in April 2019. We saw a chaperone log was kept for all patients who had undergone a transvaginal scan. A transvaginal scan is a type of pelvic ultrasound used to examine female reproductive organs.

At the time of our inspection, information regarding safeguarding from abuse was not displayed where people using the service would see it. Following our inspection, the service informed us this information was now displayed within the clinic for service users to see.

Cleanliness, infection control and hygiene

The service controlled infection risk well. Staff used equipment and control measures to protect patients, themselves and others from infection. They kept equipment and the premises visibly clean.

All clinical areas were clean and had suitable furnishings which were clean and well-maintained. All clinical areas were visually clean, tidy and uncluttered. All surfaces, flooring and equipment were wipeable and cleaned in line with manufacturers guidance. The premises appeared well maintained and had recently been redecorated and new floor coverings provided. This was an improvement since our last inspection.

Cleaning records were up-to-date and demonstrated that all areas were cleaned regularly. During our inspection we saw up-to-date cleaning schedules for the employees and the external cleaning company who provided weekly cleaning via a service level agreement. These included what cleaning was required, how often and by whom.

Staff cleaning checklists were complete. These included daily, weekly and monthly tasks as appropriate. We saw evidence the checklists had been completed consistently since May 2019.

The provider had a small selection of toys available for children to play with for the weekly coffee morning. We saw evidence the toys were cleaned weekly by staff following the coffee morning.

Staff followed infection control principles including the use of personal protective equipment (PPE).

The organisations infection prevention and control policy had been updated in April 2019 and included reference to national guidance and best practice. The policy included clearly defined aims and scope along with clear guidance to roles and responsibilities for tasks and cleaning requirements.

At our last inspection the service did not have any systems or processes to ensure hand hygiene was carried out. Since then the service had introduced robust systems and processes. The hand hygiene policy included the world health organisation (WHO) guidelines on hand hygiene in health care. The five moments of hand hygiene poster along with guidance on how and when to use hand sanitiser was displayed in clinical areas. During our inspection we saw hand hygiene audits had been undertaken monthly for all staff from June to September 2019.

Hand washing facilities were available in each scan room along with gloves and aprons. Hand sanitiser was available throughout the premises as well as both inside and outside of each clinical room. The hand sanitisers in use had the date opened recorded on the bottle and all were in date of the time limit identified by the

manufacturer. During our inspection, we observed staff adhering to infection control principles. For example, all clinical staff were bare below the elbows, washed their hands and used alcohol gel appropriately in line with the providers infection prevention and control policy.

The provider managed clinical waste and hazardous material safely. There was a service level agreement with an external provider to dispose of clinical and hazardous waste. Clinical waste bins with lids were in each scan room and labelled in line with the providers clinical waste policy. Yellow clinical waste bags and black general waste bags were in use within the service to appropriately mange differing waste types. Sharps bins were labelled, not over filled with the partial closer in place.

Staff cleaned equipment after patient contact.

A cleaning checklist to be completed after each patient was in place for each scanning room. We saw evidence this had been completed consistently since April 2019. The checklist included the need to use PPE, cleaning of couch and replacement of the disposable bed cover, cleaning of the ultrasound probe and machine, cleaning of any surfaces used and the safe disposal of sharps. During our inspection we observed two scans and saw the cleaning checklist being followed.

The organisation had a decontamination process for the cleaning of transvaginal (TV) probes following use. The guidelines were based on guidance from the British Medical Ultrasound Guideline 2019 and used a recommended duo system. A cleaning log was in place where the decontamination of the TV probe following each use and at the start and end of each day was recorded. The record included the time and date of cleaning, patient details and the lot number of the duo product used.

Environment and equipment

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

The design of the environment followed national guidance. The service was located on the ground floor of a retail unit on a public street. It had a reception area, large waiting room, two scan room, toilets and a staff kitchen. The rooms were accessible to all women and visitors, including those with physical disabilities.

The examination couch was height adjustable. There was a large wall mounted monitor at the end of the couch so women and those attending them could view the scan from all areas of the room. All electrical wires were securely contained behind the ultrasound machine.

The scanning rooms had a sign on the door to notify people when it was in use.

The service had enough suitable equipment to help them to safely care for service users. The service's ultrasound machine was maintained and regularly serviced by the manufacturers. We reviewed the service level agreement and the service records for the equipment, which detailed the maintenance history and service due dates of equipment.

The provider had access to two machines. Therefore, if there was a failure in one machine women would not experience prolonged delays to their care and treatment due to equipment being broken and out of use.

All equipment conformed to relevant safety standards. Non-medical portable appliance electrical equipment was tested.

The service had a first aid kit available. Upon checking we found all the contents to be in date.

Staff stored substances which met the 'Control of Substances Hazardous to Health' (COSHH) regulations in a locked cupboard. However, the COSHH risk assessments were not completed.

Staff carried out daily safety checks of specialist equipment. We saw each scanning room had a daily safety checklist for the scanning machine and these had been consistently completed.

The service had suitable facilities to meet the needs of patients' families. The scan rooms had adequate seating for those attending the scan with the woman, including wipeable chairs. Staff had enough space to move around the ultrasound machines for scans to be carried out safely.

The environment for taking blood for any testing was appropriate. Blood was taken while the women were in

the scan room. Sharps were disposed of appropriately in sharps bins which were available in each scan room. The sharps bins were labelled appropriately with half closures in place and not overfilled.

Staff labelled bloods taken with the individual's details and checked with them prior to sending off for testing. The bloods were sealed in a foil pack and posted to the testing laboratories on the same day by recorded delivery.

Staff disposed of clinical waste safely.

Assessing and responding to patient risk

The service had appropriate arrangements in place to assess and manage risks to women, their babies, and families.

Staff shared key information to keep women safe when handing over their care to others. There were clear processes to guide staff on what actions to take if any suspicious findings were found on the ultrasound scan. If they had concerns, the sonographer followed the service's referral pathway and referred the woman to the hospital where they were receiving antenatal care, with their consent. For example, if the sonographer could not detect a heartbeat they would ring the appropriate hospital and arrange an urgent appointment for the women to attend the antenatal clinic. Women were provided with a report completed by the sonographer which included details of findings along with referral note.

During our inspection, we reviewed one referral form as others were secured in a locked filing cabinet and the key was not available. This contained a description of the scan findings, the reason for referral, who the receiving healthcare professional was and details of the appointment.

Staff made sure women understood the ultrasound scans they provided were in addition to their routine maternity care and advised any woman who had missed a 12-week scan to register with a midwife.

Staff completed risk assessments for each woman on arrival. All women completed a pre-scan questionnaire that included pregnancy history. This included a declaration signed by the woman which gave consent to pass medical information to an NHS care provider if needed and a confirmation they were receiving appropriate pregnancy care from the NHS.

The service used the 'Paused and Checked' approach devised by the British Medical Ultrasound Society (BMUS) and Society of Radiographers. We saw the sonographer completed checks during scans, which included confirming the woman's identity and consent, providing clear information and instructions, and informing the woman about the results.

Scans were carried out following 'As Low As Reasonably Achievable' (ALARA) guidance and women were given the information which allowed them to make informed decisions about the risk of scanning. Before carrying out any scans, the sonographer asked if they had been feeling unwell or experienced any pain or bleeding. If the women disclosed they had experienced any symptoms, then they were referred to their midwife or hospital for further investigation and the scan would not go ahead.

We observed that scan reports were completed immediately after the scan had taken place and given to the women to take away and a link to the images would be sent to a designated mobile phone. The link would be active for 28 days to allow clients to download the report and images. The reports were also recorded on the scan machines for service records for three months.

We saw a written risk assessment for women who were offered a transvaginal (TV) scan. Women signed the forms to confirm they were not suffering from any of the listed conditions that would make the TV procedure unsafe. The conditions listed included heavy vaginal bleeding, recurring miscarriage, vaginal infection or irritation, history of cervical incompetence and high-risk obstetric history.

The service only used latex-free covers for the TV ultrasound probe, which minimised the risk of an allergic reaction for women with a latex allergy.

Due to the nature of the service, there was no emergency resuscitation trolley on site. However, staff could access a first aid box and the registered manager had up-to-date first aid training. In the event of a patient becoming acutely unwell, the service would call 999.

Staffing

Good

Diagnostic imaging

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

The service had enough staff to keep women who used the service safe. The staff comprised of one registered sonographer who was also the owner and registered manager, two receptionists and a clinic manager. The provider employed an independent self-employed sonographer if demand for service was high or cover was needed for holidays.

The service operated with a minimum of three staff on site. This comprised of the qualified sonographer at least one receptionist and the clinic manager or a second receptionist if the clinic manager was not on duty.

The service did not use agency staff. In the event a staff member was sick, the service would cover from within the team if possible. In circumstances where this was not possible, then the clinic list would be reviewed and amended as appropriate. This could include the clinic running longer to help prevent cancellations.

During our inspection, we saw evidence in the permanent staff and the self-employed sonographer's personal file that they had appropriate skills, knowledge and training to ensure women using the service were given safe care at all times. We saw certificates confirming the training and updates they had attended.

Records

Staff kept detailed records of patients' care and treatment. Records were clear, up-to-date, stored securely and easily available to all staff providing care.

Women's notes were comprehensive, and all staff could access them easily. Staff kept detailed records of women's appointments, referrals to NHS providers and completed scan documents. Records were clear, included appropriate information, were up-to-date and only available to those who needed them.

Records were stored securely. Access to the ultrasound machine was password protected and restricted to the registered manager and sonographer. Images were stored on the machine for up to three months then were automatically deleted.

Staff gave ultrasound images to women at the end of their appointment. Depending on the type of scan, the service sent a text link to the images which enabled women to have instant access to and save their scan images.

Unborn babies' heart beat could be recorded on a small electronic device during the scan which could be inserted into a heartbeat teddy bear for the women to take home. If the women decided not to buy the heartbeat bear, the recording was deleted.

Medicines

The provider told us they did not store or administer any medicines.

Incidents

The service managed patient safety incidents well. Staff recognised and reported incidents and near misses. Managers investigated incidents and shared lessons learned with the whole team and the wider service. When things went wrong, staff apologised and gave patients honest information and suitable support.

Staff knew what incidents to report and how to report them**.** During our last inspection staff could not recognise what constituted an incident. Since then, training on incident reporting had improved and staff we spoke with could describe their roles and responsibilities in relation to raising concerns, recording, investigating and providing feedback after safety incidents.

All staff we spoke with described the process for reporting incidents and provided examples of when they would do this, such as information governance breaches or equipment breakdown. The process for incident reporting and investigating was outlined in the service's incident reporting policy.

Incidents were not recorded or investigated at our last inspection, therefore any lessons learned were not shared with staff. The service now recorded incidents in an incident book which was available in the service for staff to access. The clinic manager was responsible for conducting investigations into all incidents. The outcome of investigations and learning points were shared with staff at their weekly team meeting. During our inspection, we saw meeting minutes that confirmed this.

Good

Diagnostic imaging

The service reported one incident from April to October 2019. Staff we spoke with described the incident and outcome.

From October 2018 to December 2019 the service had no never events. A never event is a serious incident that is preventable and has the potential to cause serious patient harm or death.

The service did not report any serious incidents from October 2018 to October 2019.

Regulation 20 of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014 requires the organisation to be open and transparent with a patient when things go wrong in relation to their care and the patient suffers harm or could suffer harm, which falls into defined thresholds. Duty of Candour is a regulatory duty that relates to openness and transparency and requires providers of health and social care services to notify patients (or other relevant persons) of certain 'notifiable safety incidents' and provide reasonable support to that person.

Staff had received duty of candour training since our last inspection and now understood the need to be open and honest with clients. The registered manager could explain the process they would undertake if they needed to implement the duty of candour following an incident, which met the requirements. However, at the time of our inspection, they had not needed to do this. The duty of candour regulation only applies to incidents where severe or moderate harm to a patient has occurred.

Are diagnostic imaging services effective?

We do not rate effective.

Evidence-based care and treatment

The service provided care and treatment based on national guidance and evidence-based practice. However, not all policies were up-to-date.

Staff followed policies to plan and deliver high quality care according to evidence-based practice and national guidance. Most of the service's policies and protocols were up-to-date and had been written by a clinic manager and the registered manager. The provider was in the process of reviewing the policies that required updating.

The service followed national guidance from The National Institute for Health and Care Excellence (NICE) and British Medical Ultrasound Society (BMUS). They did not participate in any benchmarking clinical audits.

As low as reasonably achievable (ALARA) principles, outlined in the 'guidelines for professional ultrasound practice, 2017' by the Society and College of Radiographers (SCoR) were followed by the service. To help reduce ultrasound dose to women, sonographers, where possible, did not scan for longer than 10 minutes, and did not repeat a scan for seven days.

The service had an equality and diversity policy issued in June 2019. Staff were trained on equality and diversity as part of their induction, with annual updates, to ensure they did not discriminate when making care and treatment decisions. We saw a signature sheet evidencing all staff had also completed an equality and diversity workbook.

Women were told when they needed to seek further help. The service followed a referral pathway when an anomaly (abnormality) was identified. The pathway included making a confidential appointment with the hospital providing the women's antenatal care. Staff informed and updated women with the process and reasons for the referral.

Nutrition and hydration

Staff gave patients and people accompanying them drinks as required. The service offered hot drinks to women and people accompanying them. They also stocked biscuits which they offered in an emergency for a diabetic.

Pain relief

The service did not monitor or administer any pain relief.

The service did not offer pain relief or assess pain as the procedure was pain free. However, we saw staff asking women how they were, and if they were comfortable when in the waiting area and in the scanning room during the ultrasound scan.

Good

Diagnostic imaging

Patient outcomes

The service did not monitor all aspects of effectiveness of care and treatment.

The service did not carry out audits into the quality of ultrasound scanning undertaken and the reports generated. The service did not have any arrangements for peer review of scans and reports. Peer review is the evaluation of work by one or more people with similar skills and competence as the producer of the work. However, since our inspection the provider has told us a process is now in place working with other local businesses to peer review a selection of scans annually.

Monitoring of patient outcomes and experiences occurred by reviewing patient satisfaction feedback which was via feedback cards, social media, company website and face-to-face conversations. The feedback cards were available for women and those accompanying them in the reception area.

Referrals made to the NHS by the service were retained and stored securely. However, they were not audited to ensure quality.

Due to patient confidentiality and Data Protection (DP) regulations, the service does not receive an outcome from the NHS.

Competent staff

The service made sure staff were competent for their roles. Managers appraised staff's work performance.

Managers gave all new staff a full induction tailored to their role before they started work. When first employed, staff undertook induction training which comprised both face-to-face and online learning. Staff completed annual mandatory training, which included ongoing training as required, and third-party training courses in key areas.

Staff were experienced, qualified and had the right skills and knowledge to meet the needs of women. At the time of our inspection, the service employed one sonographer. A second self-employed sonographer who provided support if the demand for the service was high or to provide cover for annual leave. We reviewed their staff files, and both were qualified with post graduate certificates in sonography.

We saw evidence the sonographers had attended sonography updates delivered by external providers twice in the last six months.

The sonographer carried out non-invasive prenatal tests (NIPTs) and explained and discussed the associated benefits and limitations of the tests. NIPTs are blood tests for screening unborn babies' risk of certain chromosome conditions such as downs syndrome. Women undergoing NIPTs attended the service to request this test to be carried out. They were given written information by the provider regarding the testing kit, with clear explanation of the associated benefits and limitations of the test. Women were given the opportunity to discuss these with the sonographer before the test was undertaken.

The sonographers who took blood samples for NIPTs had completed appropriate training to take blood at the local NHS Trust with the associated competencies undertaken. We saw evidence the registered manager was a member of the National Association of Phlebotomists, through which she received updates and guidance in quarterly newsletters.

Staff had the opportunity to discuss training needs with their line manager and were supported to develop their skills and knowledge. Staff felt comfortable to discuss their development with the registered manager or clinic manager, however staff also had the opportunity to discuss this formally. All staff had monthly a one to one meeting with the clinic manager. Staff were clear about the boundaries of their individual roles.

Managers supported staff to develop through yearly, constructive appraisals of their work. The service employed one member of staff who had been in post over 12 months and they had received an appraisal. Appraisals were planned for the staff employed under a year.

The service does not employ trainees or volunteers.

Multidisciplinary working

The staff worked together as a team to care for the women and those who accompanied them.

Staff held regular and effective multidisciplinary meetings to discuss women and improve their care. All staff attended a weekly meeting to review all aspects of the services' working practices. This included issues identified with actions to resolve and improve care.

Good

Diagnostic imaging

At the time of our inspection, we saw positive working relationships between the sonographer, clinic manager and receptionists. For example, we saw the receptionist and the clinic manager shared responsibility for answering the telephone and managed this effectively, so the calls were always answered.

The service had positive communication with health care professionals when communicating with NHS services to make a referral. The NHS services included four local hospitals.

The service had a policy to liaise with local safeguarding authorities when required.

Seven-day services

Services were available six days a week.

The service opened six days a week, closing on Wednesday. The service operated varying hours between 9am and 8pm, depending on the day. Sunday clinics were provided once a month from 10am to 4pm. The service accommodated for working mothers to attend either in the evening or during the weekend. The clinics ran in line with the demand of the women, enabling them to make bookings at a time to suit them. However, the service opening times on the provider's website did not reflect this, as the Sunday clinic was not listed.

Consent and Mental Capacity Act

The service had policies and procedures in place for gaining consent, staff understood how and when to assess whether a woman had the capacity to make decisions about their care and staff followed service policy when a woman could not give consent.

Staff made sure women consented to treatment based on all the information available. Staff received training on the Mental Capacity Act (MCA) as part of their induction and annual mandatory training. Information displayed within the clinic ensured they had regard to MCA code of practice when protecting people's rights.

Staff gained consent from patients for their care and treatment in line with legislation and guidance. All women received written information to read and sign before their scan. This included terms and conditions, information on what was and was not included in the scan package, information on medical records, consent and use of data. The pre-scan consent form included information that the scan was not replacing the NHS scans performed routinely during a women's pregnancy and consent to share information with the NHS if required. We reviewed two consent forms and saw they had all been fully completed with clear signed consent.

Women self-refer to the service and request a NIPTs. The leaflet provided with the blood testing pack was given to the women to ensure they fully understand the procedure and potential results before the test goes ahead. Before blood was taken, staff confirm with each woman that they have understood the written information and answered any questions.

Staff clearly recorded consent in the woman's records. All staff were aware of the importance of gaining consent from women before conducting an ultrasound scan. The sonographer confirmed names, dates of birth and scan package prior to the scan, then obtained verbal consent to begin.

Each woman attending for a scan filled in a consent form which included sections for demographic information, medical history, explained what each scan was, ultrasound safety information and what to expect. The consent form was clear that the scans undertaken did not take the place of the routine NHS scans and that all women should also attend for these.

Are diagnostic imaging services caring?

Good

We did not previously rate this domain. We rated it as **good.**

Compassionate care

Staff treated patients with compassion and kindness, respected their privacy and dignity, and took account of their individual needs.

Staff were discreet and responsive when caring for women. Staff took time to interact with women and those close to them in a respectful and considerate way. During our inspection, we saw staff immediately build a rapport with women and families, encouraging a calm and reassuring environment. All staff treated women with dignity and respect and provided compassion throughout their scan journey.

We observed the sonographer being very patient with women. During one scan we saw staff being particularly patient and explaining the process to a client with specific medical needs.

Women said staff treated them well and with kindness. We spoke with three woman and people who accompanied them. They all spoke positively of the service and described their experiences as good. One woman we spoke with had used the service for her previous pregnancy and even though they had moved 20 miles away, they decided to return for their second pregnancy.

We observed staff introducing themselves to women and people who accompanied them. Receptionists provided detailed information of the scan package chosen and all the available optional extras. The receptionists were polite and friendly towards women and clearly explained appointments to women and what to expect.

Emotional support

Staff provided emotional support to patients, families and carers to minimise their distress. They understood patients' personal needs

Staff understood the emotional and social impact that a person's care, treatment or condition had on their wellbeing and on those close to them. We observed staff spoke with women in a sensitive and calming way. From the reception/waiting area through to the scan room, there was a very relaxing atmosphere throughout the clinic.

Staff gave women and those close to them help, emotional support and advice when they needed it. If a scan identified any issues with the pregnancy, staff explained the results to women and those who accompanied them, in a supportive way. The sonographers referred them to the NHS provider explaining the process of the referral, arranged an appointment with the NHS provider, and answered any further questions women had.

Staff supported patients who became distressed in an open environment and helped them maintain their privacy and dignity. Staff told us if an issue with a pregnancy was found then the women and any person accompanying them would be given time to ask questions even if this meant that the appointment overran. They would be able to stay in the privacy of the scanning room for as long as they needed as the service had two scanning rooms available, so activity was moved to the second room.

Understanding and involvement of patients and those close to them

Staff supported and involved patients, families and carers to understand their condition and make decisions about their care and treatment.

Staff made sure women and those close to them understood their care and treatment. Staff took time to explain the procedure before and during the scan and checked the scan package chosen by women and those accompanying them. We saw the sonographer explained what was happening throughout the scan. They used appropriate language to clearly explain the position of the unborn baby and the images on the monitors. We observed one early scan where the sonographer could not identify the unborn baby during the scan. The sonographer explained that they would move to a transvaginal scan, checking the woman was happy to continue, they then positively identified the baby.

The sonographer asked women if they had any questions throughout and at the end of the scan. Women told us that both they and their family had felt involved in the scan, and any questions they had were answered in a way they understood.

Staff talked to women in a way they could understand, using communication aids where necessary. During our visit staff communicated with women and people who accompanied them, in a way they could understand. We saw staff encouraged family members to identify features on the scan and took the time to engage in conversation by asking them about the pregnancy. For example, we saw staff asking a father if this was their first child and discussing the reaction to a new born baby.

The service assured women that their scan images were treated confidentially. Staff sent women a unique link to their scan images via the mobile phone application. When the application was downloaded, women could access and download their scan pictures onto their mobile telephone within 28 days. Women then could download and save the scans to their computers and choose who to share them with.

Good

Diagnostic imaging

Patients gave positive feedback about the service. We saw there had been 96 positives comments since May 2019 about care received on various forums, including social media and paper-based reviews. For example, we saw comments including "I love this place they are brilliant amazing people ", "all the staff are really friendly" and "person centred, safe, caring environment, where you feel relaxed and at ease".

Are diagnostic imaging services responsive?

Good

We had not previously rated this domain. We rated it as **good.**

Service delivery to meet the needs of local people

The service planned and provided care in a way that met the needs of local people and the communities served. It also worked with others in the wider system and local organisations to plan care.

Facilities and premises were appropriate for the services being delivered. The facilities and premises met the needs of women and those accompanying them and ensured a patient-centred environment. This included comfortable seating in the waiting area. Accessible toilets were provided by the waiting area, with adequate signposting for each room and facility.

There was street parking available outside the clinic as well as free parking outside a nearby grocery store and library.

Information was available in accessible formats around the clinic, including posters on the walls explaining scan packages and optional available extras. Leaflets detailing other service providers were available, for example; we saw leaflets promoting fitness and exercise in pregnancy from a variety of providers.

The service offered a range of scan packages, all of which included a wellbeing scan. Costs and details of deposit and full payment was clearly explained on the website, in information at the clinic, and by staff when women attended their appointment. We observed staff providing this information when taking bookings over the telephone.

Managers planned and organised services, so they met the needs of the local population. Appointments were flexible in the evenings and at the weekends. Women could book an appointment to suit them either through the website or calling the service directly.

Following completion of a scan the service sent a link to women's mobile telephones to allow them immediate access to their scan images and allow them to save them electronically as well as providing scan images at the time of the appointment as a photograph.

Managers monitored and took action to minimise missed appointments. Bookings into the service could be made by telephone, facebook or the providers website. All women received a reminder 24 hours before their appointment by email or text to minimise missed appointments.

Meeting people's individual needs

The service was inclusive and took account of patients' individual needs and preferences. Staff made reasonable adjustments to help patients access services. They coordinated care with other services and providers.

Staff told us they provide a service to pregnant women and tailored it completely to suit women's needs. Receptionists' would greet women when they arrived for their appointment, explain their scan package and ask them to complete their consent form. The consent form included sections for demographic information, medical history, explained what each scan was, ultrasound safety information and what to expect. The consent form was clear the scans undertaken did not take the place of the routine NHS scans and that all women should also attend for these.

The service allocated enough time throughout women's appointments for them to ask any questions they had. The appointments lasted around 30 minutes, with the ultrasound scan taking around 10 minutes. We saw women were supported throughout their appointments and were not rushed at any point.

Good

Diagnostic imaging

Staff understood and applied the policy on meeting the information and communication needs of women with a disability. Women received information to read and sign at the start of their appointment. The service had a translation service online which staff could access to provide information in different languages.

The service had reasonable adjustments in place for people with a disability. The premises were located on the ground floor with enough space for wheelchair access. In the scan room, the couch could be lowered to assist women. Staff told us they had scanned women who had presented in wheelchairs due to their physical disabilities and how partners had transferred the women safely.

The service offered a range of baby keepsakes and souvenirs for woman to buy after their scan. Including, photo frames, heartbeat bears, which included a recording of the unborn babies' heartbeat, memory boxes detailing a video of the scan image to which music could be added and gender reveal products of balloons and confetti cannons.

Access and flow

People could access the service when they needed it and received the right care promptly. Waiting times from referral to treatment and arrangements to admit, treat and discharge patients were in line with national standards.

Women could access the service when required, as the service opened during the day, two evenings a week and at the weekend. Women self-referred to the service, and booked appointments at a time to suit them, either in person, by using the online appointment system, Facebook or contacting the service by telephone.

Women had timely access to results, as scan images were provided during their appointment.

The service did not have a waiting list for appointments, and at the time of our inspection there was no back log for appointments. Staff explained the booking system was flexible, and they operated clinics around times to suit women.

Staff were flexible and allowed women to change their scan package to meet their choice. Women paid a deposit to confirm their booking and received information about their chosen scan package. When women attended their appointment, they could change their scan package.

During our inspection we saw services ran on time, and staff told us they would inform women of any disruption.

Learning from complaints and concerns

It was easy for people to give feedback and raise concerns about care received. The service treated concerns and complaints seriously, investigated them and shared lessons learned with all staff. The service included patients in the investigation of their complaint.

The service clearly displayed information about how to raise a concern in patient areas.

Information on how to make a complaint was displayed in the clinic. Women could give feedback via the forms that were available in the clinic, the providers web page, Facebook and in person. We saw staff talking to clients to identify any potential dissatisfaction whilst the client was still in the clinic.

A complaint handling procedure was in place within the service. However, there was no issue, review date or document control. The procedure detailed their process of complaints and staff responsibility and stated that all complaints should be acknowledged and responded to within 21 working days.

Managers investigated complaints and identified themes. From May 2019 to October 2019 the service received five complaints which were managed under their formal complaints' procedure. We reviewed three complaints and they had all been responded to within the service's time frame with no specific themes.

Staff understood the policy on complaints and knew how to handle them. Staff explained that complaints were usually minor in nature and are usually communicated to the service via social media channels or emails which were monitored daily. Staff stated all complaints received were thoroughly investigated and actioned in line with the providers policy. We reviewed three complaints, the process undertaken, actions, outcomes and feedback given to the complainant were robust.

Good

Diagnostic imaging

Managers shared feedback from complaints with staff and learning. Learning from complaints was shared at weekly service meetings. We saw meeting minutes from a three-month period and discussion about complaints was included with updates and actions.

Are diagnostic imaging services well-led?

Good

Our rating of well-led improved.We rated it as **good.**

Leadership

Managers in the service had the right skills and abilities to run a service providing high-quality sustainable care.

The registered manager and clinic manager had the right skills and abilities to run a provider providing high-quality sustainable care. The registered manager and the clinic manager met weekly to review the service and discuss issues and looking for resolutions. This was an improvement since our last inspection.

The clinic manager had a background in office administration and had responsibility to ensure the service ran safely and in line with guidance and standards.

Managers in the service were subject to checks through the Disclosure and Barring Service prior to employment as were the rest of the staff. In addition, they required references from previous employers and employment history.

Staff told us that managers were visible and approachable, and they felt well supported. They knew the management arrangements were.

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 a clear vision and values, which was displayed in the clinic. The vison was to be the leader within the region, in private scanning for women, babies and their families. With aims and values supporting the vision. Staff we spoke with were aware of and enthusiastic to demonstrate the vision throughout their work. We saw evidence that this was discussed and supported at the weekly team meetings to ensure that all staff understood their responsibilities to ensure it was achieved. This was an improvement since our last inspection.

We saw positive interactions demonstrating the service visions and values with women and their families who were using the service from all staff.

Culture

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

All managers promoted a positive culture that supported and valued staff, creating a sense of common purpose based on shared values.

All staff we spoke with were proud of working for the service and spoke positively about the culture of the service. Staff told us they worked well together as a team and there was an open and honest culture. They felt able to raise concerns without fear of retribution.

The service had a lone worker policy issued in May 2019 and all staff had personal alarms that they always wore.

Governance

Staff at all levels were clear about their roles and accountabilities and had regular opportunities to meet, discuss and learn from the performance of the service

Since our last inspection the service had introduced governance arrangements which were clear and appropriate for the size of the service. Staff we spoke with understood the structure and responsibilities of staff within the service.

Staff discussed audit results, complaints, incidents, service changes and patient feedback at weekly team meetings. We saw evidence of this in the minutes of the weekly meetings.

The clinic manager had overall responsibility for clinical governance and quality monitoring. This included investigating incidents and responding to patient complaints. We saw evidence all incidents and complaints were reviewed and discussed with staff to improve care.

All staff were covered by the service's indemnity and medical liability insurance which was renewed annually.

The service undertook an in-depth recruitment process. All staff were checked through the Disclosure and Barring Service prior to employment. In addition, the service required references from previous employers and employment history as well as proof of any qualifications held relevant to their employment, in line with schedule 3 of the HSCA 2008 (regulated activities) regulation 2014.

The service had policies and procedures for the operation of the service which were in date, these were available to staff in a folder in the clinic. However, standardised document controls were not in place.

Managing risks, issues and performance

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

Since our last inspection the service had introduced systems to plan to eliminate or reduce risks and cope with both the expected and unexpected.

Risk assessments completed, included mitigation and control measures, who was responsible for managing the risk and review dates. We saw up-to-date risk assessments for fire, first aid and health and safety. However, at the time of our inspection the risk assessments for Control of Substances Hazardous to Health (COSHH) had not been completed.

The service did not have a risk register. When we spoke with the registered manager they were initially unable to identify any risks to the service. However, on further discussion, the risk of competition within the market and new scanning services being set up was identified. We were told this was managed by regular review of services offered and pricing.

Staff were made aware of the provider's policies on induction and changes were discussed at weekly staff meetings. During our inspection we reviewed eight policies which were all signed by each member of staff to say they had read them.

The service had a business continuity policy which outlined clear actions staff needed to take in the event of information technology (IT) failure or extended power loss. This contained key hazards and mitigations in the event of failure. The IT system was cloud based which would allow service delivery at a different location if required. Staff told us how they would respond in the event of an IT failure and the mitigation taken by the provider to minimise effect.

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 had appropriate and up-to-date policies for managing women's personal information that were in line with relevant legislation and the requirements of the General Data Protection Regulations (GDPR).

Women had access to terms and conditions of the service through their website. However reception staff were happy to provide them to anyone who did not have computer access. All packages and prices were clear on their website and were also available in the clinic. Payment methods and processes were discussed at the time of booking.

The service held nominal data on women who used the service. All held data was a combination of paper records and electronically with password entry. Any paper records were kept in a locked cupboard inside the clinic. All staff had access to the electronic and paper records.

Staff told us there were enough computers in the unit. This enabled staff to access the computer system when they needed to.

Engagement

The service engaged well with patients, staff, the public and local organisations to plan and manage appropriate services and collaborated with partner organisations effectively.

The service gathered feedback from women and families and used this to improve the service. Women could leave feedback on comments cards, online review sites and social media pages. The website included details on how women could contact the service with a section allowing a direct message to be sent to the provider. The website also showed stories of women's experience of using the service and their pregnancy. All the comments made were also very positive.

Good

Diagnostic imaging

At the weekly team meeting feedback from women was shared and discussed with staff and any actions for improvement agreed.

The service had effective relationships with the local safeguarding team, midwives and hospitals. The provider could ring any of the local hospitals and request a woman attends for an unscheduled appointment.

The service had links to local providers for access to counselling if required for staff and women using the service.

Learning, continuous improvement and innovation

All staff were committed to continually learning and improving services

The service shared learning and discussed plans to improve the service at the weekly staff meetings which had been introduced since our last inspection. We saw evidence in meeting minutes that actions were taken if any learning was identified. This was an improvement since our last inspection.

Outstanding practice and areas for improvement

Areas for improvement

Action the provider SHOULD take to improve

The provider should ensure all control of substances hazardous to health (COSHH) risk assessments are completed. Regulation 12: Safe care and treatment (2)(a).

The provider should consider how policies are managed with issue, review date and standardised document control.

The provider should consider updating the services website to reflect the services provided.

The provider should consider how to review the quality of the scans are reviewed using a system of audit and peer review. Since our inspection the provider has told us a process is now in place working with other local businesses to peer review a selection of scans annually.