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

Are services safe?	
Are services well-led?	

Summary of findings

Letter from the Chief Inspector of Hospitals

Miracle in Progress is operated by Miracle in Progress Ltd. Miracle in Progress offers a range of ultrasound scans to women throughout their pregnancy. These include early pregnancy scans, gender scans, and souvenir scans. The provider is run by a registered manager.

We carried out an unannounced focused inspection of Miracle in Progress on 16 April 2019, in response to concerning information we had received in relation to the management of the regulated activities at this provider. We carried out a further visit on 29 April 2019, to check on improvements the provider told us about following our initial inspection.

During this inspection we inspected using our focussed inspection methodology. We inspected the key questions of safe and well-led only. We did not provide an overall or key question rating at this inspection, as we did not carry out a comprehensive inspection.

Our findings were:

- The provider did not provide mandatory training in key skills to staff and did not ensure everyone completed it. Improvements were made by the time of our follow up inspection.
- Staff did not understand how to protect women and people attending the clinic from abuse. Staff had not had training on how to recognise and report abuse and therefore did not know what their responsibilities were in relation to safeguarding. We found this had improved by the time of our follow up inspection.
- The provider did not control infection risk well. Staff did not always keep themselves, equipment and the premises clean. They did not always use control measures to prevent the spread of infection. At our follow up inspection, we saw significant actions taken to address all of the concerns we found.
- There was no incident reporting process in this provider and staff did not recognise incidents. As incidents were not recorded they were not investigated incidents and therefore any lessons learned were not shared within the provider. Staff were unaware of their responsibilities in relation to duty of candour. We found at our follow up inspection this had improved and processes were in place.
- Managers in the service did not have the right skills and abilities to run a provider providing high-quality sustainable care.
- The provider had a vision for what it wanted to achieve, but this could not be articulated effectively by the registered manager, was not displayed in the location or understood by staff. There were no workable plans or strategy to turn it into action.
- The provider did not systematically improve provider quality and safeguard high standards of care as it did not have robust governance processes in place. At our follow up inspection, we found this had improved with further improvements planned.
- The provider did not have systems to identify risks, plan to eliminate or reduce them, and cope with both the expected and unexpected. We found this had improved by the time of our follow up inspection.
- The provider did not improve services by learning from when things went well or wrong as they did not have process in place to support this.

However:

- There was a culture which wanted to deliver the best possible care to women.
- The provider mostly had appropriate arrangements in place to assess and manage risks to women.

Summary of findings

- The provider had enough staff to provide the service**.**

Following this inspection, we took action under Section 31 of the Health and Social Care Act 2008, to urgently suspend the provider's registration for a period of six weeks. The notice of urgent suspension of registration was given because we believed that a person will or may be exposed to the risk of harm if we did not take this action. On 29 April 2019 we returned to carry out another inspection and subsequently lifted the suspension.

We told the provider that it must take some actions to comply with the regulations and that it should make other improvements, even though a regulation had not been breached, to help the provider improve. We also issued the provider with six requirement notice(s). Details are at the end of the report.

Amanda Stanford

Deputy Chief Inspector of Hospitals (Central)

Summary of findings

Our judgements about each of the main services

Service	Rating	Summary of each main service
Diagnostic imaging		• The provider did not provide mandatory training in key skills to staff and did not ensure everyone completed it, although this had improved by our follow up inspection. • Staff did not understand how to protect women and people attending the clinic from abuse. Staff had not had training on how to recognise and report abuse and therefore did not know what their responsibilities were in relation to safeguarding. This had improved at our follow up inspection. • The provider did not control infection risk well. Staff did not always keep themselves, equipment and the premises clean. They did not always use control measures to prevent the spread of infection. At our follow, up visit the provider had taken action to address most of these issues. • Managers in the provider did not have the right skills and abilities to run a provider providing high-quality sustainable care. • The provider did not systematically improve provider quality and safeguard high standards of care as it did not have robust governance processes in place, although we found these had improved with further improvement planned at our follow up inspection. • The provider did not have systems to identify risks, plan to eliminate or reduce them, and cope with both the expected and unexpected. At our follow up inspection, we saw this had improved.

Summary of findings

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Services we looked at
Diagnostic imaging

Summary of this inspection

Background to Miracle in Progress

Miracle in Progress is operated by Miracle in Progress Ltd. The provider opened in 2013. It is a private clinic in Loughborough, Leicestershire. The provider primarily serves the communities of Leicestershire. It also accepts patient from outside this area. Miracle in Progress offers a range of ultrasound scans to women throughout their pregnancy. These include early pregnancy scans, gender scans, and souvenir scans.

The provider has had a registered manager in post since 2013.

Our inspection team

The team who inspected the provider comprised a CQC lead inspection manager, Simon Brown and two other CQC inspectors. The inspection team was overseen by Carolyn Jenkinson, Head of Hospital Inspection.

Why we carried out this inspection

We carried out an unannounced focused inspection of Miracle in Progress on 16 April 2019, in response to concerning information we had received in relation to the management of the regulated activities at this provider. We carried out a further visit on 29 April 2019, to check on improvements the provider told us about following our initial inspection.

How we carried out this inspection

During this inspection we inspected using our focussed inspection methodology. We inspected the key questions of safe and well-led only. We did not provide an overall or key question rating at this inspection, as we did not carry out a comprehensive inspection

Information about Miracle in Progress

The premises and facilities consisted of a shop fronted facility in a shopping complex. The location is situated close to the library and adequate parking is available outside the location. The location has suitable access for people who are less able for example people who use wheelchairs.

The premises are disabled accessible and consist of a reception area with desk.

There were two clinical rooms where scanning took place, which had the necessary equipment a, couch and seating available. A wall mounted TV was fitted to the wall to enable women to see the scan whilst it was in progress. A kitchen and accessible toilet facilities were also found on the ground floor in addition to a waiting room.

The provider is registered to provide the following regulated activities:

Summary of this inspection

- **Diagnostic and screening procedures.**
- **Maternity and midwifery providers.**

All women accessing the provider self-refer to the clinic at a time to suit them. The clinic opened five days a week including evenings and at the weekend.

At the time of our inspection the clinic employed one registered manager, a clinic manager and one receptionist. The provider did not employ any medical staff. The clinic did not use or administer any medicines.

During the inspection, we visited all clinic areas. We spoke with three staff which included the registered manager, clinic manager and receptionist. We spoke with five women. We also reviewed, policies and procedures, referral forms, scan reports from the well-being and gender scan clinic and four sets of women's records during our inspection. We also reviewed information we held prior to our inspection.

There were no special reviews or investigations of the clinic ongoing by the CQC at any time during the 12 months before this inspection. The provider had been inspected once previously in 2014.

Activity (April 2018 to March 2019)

- The provider was unable to provide us with exact numbers of scans carried out during this period, however they told us on average they performed 400-450 scans per month. The provider had just started to collect numbers of scans performed at the time of our inspection.

Track record on safety (April 2018 to March 2019)

- The clinic had zero serious incidents.
- The clinic had zero never events.
- The clinic received five complaints between April 2018 to March 2019.

The clinic did not have any services provided under a service level agreement at our initial inspection our second inspection the provider had a service level agreement for the management of clinical waste.

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 found the following:

- The provider did not at our initial inspection provide mandatory training in key skills to staff and did not ensure everyone completed it. This improved at our second inspection.
- At the first inspection staff did not understand how to protect women and people attending the clinic from abuse. Staff had not had training on how to recognise and report abuse and therefore did not know what their responsibilities were in relation to safeguarding. We found this had improved at our follow up inspection.
- At our first inspection the provider did not control infection risk well. Staff did not always keep themselves, equipment and the premises clean. They did not always use control measures to prevent the spread of infection. We found improvements to this at our follow up inspection.
- At our initial inspection there was no incident reporting process in this provider and staff did not recognise incidents. As incidents were not recorded they were not investigated incidents and therefore any lessons learned were not shared within the provider. Staff were unaware of their responsibilities in relation to duty of candour. We found these areas of concern had improved on our follow up inspection.

However:

- The provider mostly had appropriate arrangements in place to assess and manage risks to women.
- The provider had enough staff to provide the service**.**

Are services well-led?

We found the following:

- Managers in the provider did not have the right skills and abilities to run a provider providing high-quality sustainable care.
- The provider had a vision for what it wanted to achieve, but this could not be articulated effectively by the registered manager, was not displayed in the provider or understood by staff. There were no workable plans or strategy to turn it into action.

Summary of this inspection

- At the initial inspection the provider did not systematically improve provider quality and safeguard high standards of care as it did not have robust governance processes in place. We found some improvements with further improvements planned at our follow up inspection.
- At our initial inspection the provider did not have systems to identify risks, plan to eliminate or reduce them, and cope with both the expected and unexpected. We found this had improved at our follow up inspection.
- At our initial inspection the provider did not improve services by learning from when things went well or wrong as they did not have process in place to support this. We found some improvements on our follow up inspection.

However:

- There was a culture which wanted to deliver the best possible care to women.

Diagnostic imaging

Safe

Well-led

Are diagnostic imaging services safe?

Mandatory training

At our initial inspection, the provider did not always provide mandatory training in key skills to staff and did not ensure everyone completed it. We found improvements on our return inspection.

- At our initial visit the provider did not have a mandatory training programme, nor did it have a mandatory training target. The clinic employed two staff in addition to the registered manager. Two out of three staff had not completed any mandatory training.
- The registered manager told us they had attended mandatory training at the local NHS trust but could not provide evidence of attendance or the course content on the day of our inspection.
- We revisited the service 13 days later and found the registered manager had implemented mandatory training in key skills to all staff and had facilitated staff to complete it. Modules completed included, health and safety, equality and diversity and infection prevention and control. An electronic flagging system had also been implemented to record all staff's mandatory training and renewal dates.

Safeguarding

At our initial inspection, staff did not understand how to protect women and people attending the clinic from abuse. Staff had not had training on how to recognise and report abuse and therefore did not know what their responsibilities were in relation to safeguarding. We found improvements to this at our follow up inspection.

- The provider had a safeguarding policy in place which was not reviewed regularly and was not up to date. The safeguarding policy did not make reference to the latest guidance and did not have up to date contact details on how a referral should be made. Not all staff were aware of the safeguarding policy and how to access it. We found an updated safeguarding policy which met the requirements expected at our follow up inspection.
- It is the duty of healthcare organisations to ensure that all health care staff have access to appropriate safeguarding training to ensure staff understand the clinical aspects of child welfare and information sharing. The Safeguarding children and young people: roles and competences for health care staff intercollegiate document 2014, sets out the requirements related to roles and competencies of staff for safeguarding vulnerable children and young people. Level 2 training is required for all non-clinical and clinical staff that had any contact with children, young people and/or parents/carers.
- At the time of our inspection, there was no provision made for the receptionist or clinic manager to undertake safeguarding training, and no risk assessment had been made to mitigate this risk. There was no one trained in safeguarding initially when we arrived to inspect the provider despite the provider being in operation, children and adults were in the provider at the time. At our follow up inspection 13 days later, we found staff knew and understood how to protect women and people attending the clinic from abuse. We saw evidence the registered manager had undergone level 3 safeguarding training for both children and adults and was the nominated safeguarding lead. The clinical manager had been trained to level 2 and the receptionists to level one
- The provider had placed a referral guide document in the office on how to refer to the local safeguarding authority for all staff.
- The registered manager was not aware they were the designated safeguarding lead and could not confirm they had received training to the correct level for both adults and children.
- At our initial inspection staff did not know their responsibilities, how to recognise a potential safeguarding issue or know the actions they should

take. Staff were not knowledgeable about Child Sexual Exploitation (CSE) and Female Genital Mutilation (FGM). Staff were not confident or trained to identify and raise such a concern if required, the registered manager, however said they had not experienced a concern of this nature at the clinic. During our follow up inspection 13 days later, we found that staff were knowledgeable about Child Sexual Exploitation (CSE) and Female Genital Mutilation (FGM). Staff were trained to identify and raise safeguarding concerns if required.

- The provider required all staff have a Disclosure and Barring Provider (DBS) checks as part of the recruitment process. We saw all staff had a DBS check at the time of our inspection.
- The provider had their own chaperone policy, which we were not assured was up to date. It had not been updated since 2015. Staff were not chaperone trained therefore staff did not know their responsibilities as a chaperone and would not be confident to report any issues. Following our inspection, we were informed and saw evidence that the clinic manager and receptionist had been booked on to a chaperone e-learning course. At our follow up inspection 13 days letter we found the provider had updated their own chaperone policy. Staff were chaperone trained and could advise on the training they received. The provider showed us a documentation log that had been devised to record any refusals for a chaperone.

Cleanliness, infection control and hygiene

At our initial inspection, the provider did not always control infection risk well. Staff did not always keep themselves, equipment and the premises clean. They did not always use control measures to prevent the spread of infection at our initial inspection. We found improvements at our follow up inspection.

- At our initial inspection the organisation's infection control policy was not fit for purpose. It did not have all the relevant information within it to support staff in adopting best practice. The policy did not cover all of the essential elements of the Health and Social Care Act 2008: Code of Practice for health and adult social care on the prevention and control of infections and related guidance such as it did not clearly define specific roles and responsibilities for cleaning; clear, agreed and available cleaning routines; sufficient resources dedicated to keeping the environment clean and fit for purpose and waste management. There was no auditing of compliance with the policy. At our follow inspection we found the provider had taken action to address the key issues within the policy and was working to fully overhaul the policy as soon as possible. We saw a hand cleaning policy and procedure had been introduced and reviewed paperwork for planned hand hygiene audits.
- There were insufficient measures in place to prevent the control and spread of possible infections. There was no standard cleaning schedule, no evidence to suggest when the environment or equipment was last cleaned and by what means. There were no cleaning schedules in place at the provider. The clinic manager told us that cleaning was contracted to an external company, but that they did not know what was expected of them. At our follow up inspection 13 days later, there was a cleaning rota with staff names and the cleaning required of them with the regularity required.
- There was no infection control risk assessment to identify control measures staff should use to prevent the spread of infection. At our follow up inspection this had been rectified.
- Staff had not been trained in infection prevention or control practices. At our follow up inspection 13 days later, we found staff had been trained in infection and control practices and the provider was trained in infection control and prevention to level three.
- We found varying degrees of cleanliness in the provider. In both scan rooms we found the tv monitor visibly dirty and full of dust.
- The infection control policy stated equipment and machines should be cleaned following each use with sanitising powder or another branded product, however we did not see any of these products available in the provider. It also stated when cleaning equipment aprons should be used. There were no aprons available in the provider at the time of our inspection and on the one occasion when we saw a machine being cleaned an apron was not worn. Staff were therefore not following the provider policies.

Diagnostic imaging

- We found inconsistencies in the cleaning of equipment after each scan, we observed two scans. Following one scan the machine was not cleaned prior to the next patient appointment. There was no documentation to support the machines were clean and ready for use on a regular basis. The couches were covered with paper towels prior to each scan, however this did not cover the entirety of the couch and we did not see this was cleaned before the next scan.
- Hand cleansing gel was available at the entrance to each scan room and in various places throughout the provider, however we noticed that the tips of the gel dispensers were visibly dirty and encrusted and they had exceeded their expiry date in 2017. We spoke with the registered manager about this who informed us this was because the dispensers were refilled when empty rather than replaced. We did not see any replacement gel available in the provider at the time of our inspection. At our follow up inspection, we found this had be rectified with new in date hand gel dispensers now in place.
- We entered a scan room following a scan which had just taken place, we asked the staff member how they had decontaminated their hands following the scan, they told us they had used the sink which was present in the room. We noticed the sink was dry, the hand soap dispenser was empty, and no hand drying towels were available in the dispenser, we were therefore not assured appropriate hand hygiene had taken place.
- Not all scan rooms were fitted with hand washing facilities at the time of our initial inspection. We found they were at our follow up inspection.
- There were no hand hygiene or infection control audits carried out in the 12 months preceding our inspection, however we saw at our follow up inspection how these were planned to be carried out.
- Scan rooms were carpeted or had rugs within them and some furniture was not wipeable such as the sofas in scan room two and the chairs in scan room one. This posed a risk to patients from cross contamination. The provider offered blood tests in these room. There was a possible risk of contamination of this furniture which could not be decontaminated. There was no deep clean schedule in the provider. At our follow up inspection 13 days later, we found significant action had been taken to ensure the environment was compliant, this included, for example, all sofas and soft chairs in the scanning rooms replaced with white plastic chairs that were easily cleaned. In scanning room one, the carpet had been replaced with non-slip non-carpet flooring. All rugs had been removed from the clinic and the carpet in reception had been steam cleaned throughout. The clinic had also been painted throughout and all posters removed.
- We were not assured sharps bins were disposed of in a timely manner and no robust process for carrying this out. We found a number of full sharps bins stored throughout the provider which had not been disposed of. The sharps bins had also not been labelled or signed in line with best practice. The registered manager told us sharps bins were taken to the local pharmacy or hospital for disposal once full. We were not assured this was the case.
- There were inadequate processes in place for the management of clinical waste. There were no facilities for the disposal of clinical waste at the registered location nor did the provider have a clinical waste disposal contract. The registered manager initially told us that they did not have “yellow” [clinical waste] bags and that all clinical waste was removed from the provider by herself, taken home and disposed of in the household waste bin. We asked what would happen to probe covers such as those used in internal examinations, she informed us she took these home, to be burned. Later, in the inspection we noticed a yellow clinical waste bag in the scan room, the registered manager told us they did have yellow bags, but no waste management contract. We found no other yellow bags available in the provider. This posed a risk to the health and safety of the general public, the registered manager and women using the provider. When we returned 13 days later we found there were new processes in place for the management of clinical waste. We saw two five litre clinical waste disposal bins in the clinic and the provider showed us the clinical waste disposal yearly contract.

Diagnostic imaging

- At our follow up inspection, we found the provider had covered the scanning machines, when they were not in use, with wipeable sheets which could easily be cleaned.
- At our follow up inspection, we found readily accessible gloves and aprons fitted to the scanning room walls available for staff.

Environment and equipment

The provider mostly had suitable premises and equipment, however scan equipment was not always checked prior to use and some consumables in the provider were found to be out of date.

- The waiting area was comfortable and pleasant with sufficient seating for people waiting. There were toys available for young children. The door to the scan rooms were kept closed during consultations and examination. The scanning rooms did not have a sign on the door to notify people when it was in use.
- Scan rooms and store rooms were cluttered and posed a risk to fire safety. We saw one store room stacked with boxes. There was no fire risk assessment for this room and no smoke detector present in the room. The room was adjacent to the main waiting room.
- Fire extinguishers were in date and available throughout the location. A recent fire compliance assessment had been undertaken and a certificate displayed within the provider.
- Staff told us they checked the scan equipment daily, however there was no effective system for recording daily checks on the equipment, therefore we had no assurance the equipment was in good working order and would not place women at risk of harm. We reviewed one chart we found in a scan room on the day of our inspection and noticed the staff member had completed the check following several scans in the room. The remaining pages were blank indicating no tests had been carried out previously. We asked for past copies of these records for both scan rooms but were told they were not available.
- The provider's ultrasound machines were maintained and regularly provided by the manufacturers. We reviewed the provider records for the equipment, which detailed the maintenance history and provider 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.
- We checked various consumables stored in the scan rooms. In one room we found 13 out of date blood bottles and in another room, we found 6 out of seven blood testing kits had expired. Staff had no oversight of expiring consumables. The registered manager told us they would check the expiry date prior to using the consumables. We were not assured this would be the case as there was no process to support this. At our follow up inspection 13 days later, we found all out of date items had been removed and all equipment and areas were visibly tidy.
- The provider had a first aid kit available.

Assessing and responding to patient risk

The provider mostly had appropriate arrangements in place to assess and manage risks to women.

- Women who presented at the clinic were generally well. There was no escalation policy for women who appeared unwell or displaying medical symptoms, and no risk assessment to mitigate this risk. However, the provider advised women to speak with their GP if they had concerns. If they became unwell in the clinic the provider would call 999.
- Where there were unexpected or significant findings during the scan procedure for pregnant women, the provider liaised directly with the local hospital where urgent care was required, for example; if the baby's heart beat was not detected during the scan, and for any other potential concern. Women were advised to continue with their NHS scans as part of the maternity pathway. Staff documented referrals on dedicated referral forms.
- During our inspection, we reviewed referral forms. All contained a description of the scan findings and the reason for referral.

Diagnostic imaging

- There was no basic life support equipment on site to use in an emergency if a person collapsed or became very unwell, and no risk assessment made to mitigate the risk of not having this.
- The provider did not use the 'Paused and Checked' checklist devised by the British Medical Ultrasound Society (BMUS) and Society of Radiographers. We observed two scans neither of which followed this process. The 'Paused and Checked' process should include confirming the woman's identity and consent, providing clear information and instructions, and informing the woman about the results.

Staffing

The provider had enough staff to provide the service.

- The clinic had one sonographer (the registered manager) the clinic manager and a receptionist. The clinic manager and receptionist had been in post approximately three weeks prior to our inspection
- There was no lone working policy in the provider. The receptionist would often be on their own at various points throughout the day, when not alone they were isolated from the main office and scan room. There was no risk assessment carried out to minimise risks associated with lone working. When we returned 13 days later we observed all staff wearing 'personal attach alarms', to reduce risks associated with lone working. The service also devised an up-to-date employee handbook policy which provided support to all staff.
- The registered manager told us that they were looking to employ locum staff to support with some aspects of the regulated activity and to support with scans as activity had increased over the last few months. At the time of the inspection there were no locum staff employed by the provider.

Records

Staff kept detailed records of patients' care and treatment. Records were clear, up-to-date and easily available to those who needed them, however records were not always suitably stored.

- The provider did not have an up-to-date information governance policy in place for staff to refer to. Therefore, staff were not aware of their responsibilities and documentation standards. The provider did not have a retention policy detailing staff responsibility, record security measures and retention periods.
- 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.
- Access to the ultrasound machine was password protected and restricted to the registered manager. Images were stored on the machine for up to three months then were automatically deleted.
- Throughout the clinic we found various pieces of patient identifiable information not stored in line with general data protection requirements, for example in scan room two we found patient's record and consent form from 2016 stored in an unlocked drawer, in an unattended room adjacent to the main corridor and waiting area. In the same room we found a number of scan pictures in drawers and some scan information for one client due to attend that day printed on the scan machine.
- The provider did not carry out documentation audits.
- The ultrasound images could be purchased by the woman at the end of her appointment. They were also emailed images which enabled women to have instant access to their scan images.
- Unborn babies' heartbeat 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 or controlled drugs however in one scan room we found a small blue table attached to a consent form in an unlocked drawer. We asked the registered manager what this tablet was for and why it was stored in this way. We were informed it had been found in the clinic and had been placed in this drawer and forgotten about, and that they did not know what the tablet was for.

Diagnostic imaging

Incidents

Initially there was no incident reporting process in this provider and staff did not recognise incidents. As incidents were not recorded they were not investigated incidents and therefore any lessons learned were not shared within the provider. Staff were unaware of their responsibilities in relation to duty of candour. We found improvements at our follow up inspection.

- The provider did not have appropriate processes for staff to raise concerns and report incidents. Staff did not understand their roles and responsibilities to raise concerns and record safety incidents. At our follow up inspection 13 days later, we found staff could recognise incidents and follow the incident reporting process which had been implemented.
- The provider did not have an accident or incident book for staff to access, if required. The registered manager said they had previously had one but was unable to produce this to the inspection team. The clinic manager told us they were expecting a new book to arrive imminently. The registered manager told us they would conduct investigations into all incidents, however said that no incidents or concerns had been raised to investigate. At our follow up inspection, we found the accident/incident book had arrived.
- Regulation 20 of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014 is a regulation which was introduced in November 2014. This regulation 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.
- Staff did not understand the duty of candour and the need for being open and honest with women and their families if errors occurred. The registered manager could not explain the process they would undertake if they needed to implement the duty of candour following an incident, which met the requirements. Duty of candour is a regulatory duty that relates to openness and transparency and requires providers of health and social care providers to notify patients (or other relevant persons) of certain 'notifiable safety incidents' and provide reasonable support to that person. During our return inspection we found staff had been trained and were aware of their responsibilities in relation to duty of candour and understood the need for being open and honest with women and their families if errors occurred.
- The registered manager was unaware of the requirements for reporting incidents to the CQC using the statutory notification route if this met the criteria, under Regulation 18 of the Care Quality Commission (Registration) Regulations 2009.

Are diagnostic imaging services well-led?

Leadership

Managers in the provider did not have the right skills and abilities to run a provider providing high-quality sustainable care.

- The provider was not well led. We were concerned that the leaders of the provider did not have the skills, knowledge or experience to lead a provider providing high-quality sustainable care. This was because they demonstrated a lack of understanding of their responsibilities in terms of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014 (Part 3).
- A registered manager oversaw the day to day running of the provider and had recently appointed a clinic manager to support the registered manager in the day to day running of the provider.
- The provider was small, and leaders did not focus on developing strong systems to support quality. They instead focused on provider delivery.
- We were not assured the manager of the provider understood the challenges of good quality care and as such did not take all of the actions needed to address them such as infection control, environmental issues and staff training.

Vision and strategy

The provider had a vision for what it wanted to achieve, but this could not be articulated effectively by the registered manager, was not displayed in the provider or understood by staff. There were no workable plans or strategy to turn it into action.

- The provider had a vision for what they wanted to achieve but no clear plans or strategy to turn it into action.
- The registered manager told us the vision for the provider was articulated in the statement of purpose submitted to the CQC and could not articulate this to us at our inspection. The vision was not displayed in the clinic and staff (although new) were not familiar with the vision. We reviewed the statement of purpose prior to our inspection which stated, 'Miracle in progress endeavours to offer the upmost professional and high-quality provider in the area of 3d/4d ultrasound scanning'.
- Although there was no formal written vision, values or strategy displayed in the provider or articulated by staff, staff shared a set of values which was around ensuring the best possible experience for women and their families.

Culture

There was a culture which wanted to deliver the best possible care to women.

- All staff in the provider demonstrated a caring attitude to want to deliver the best care they could to the women using the provider.
- Throughout our inspection, the clinic manager responded positively to feedback and asked about improvements that could be made to the provider. There was a drive from the clinic manager to improve providers.

Governance

The provider did not systematically improve provider quality and safeguarded high standards of care as it did not have robust governance processes in place. We saw some improvements at our follow up inspection.

- There was no robust governance framework in place to support the delivery of good quality care. There were no management systems in place. There was no evidence that the provider had considered the risks and challenges in the day to day of the provider. We found improvements in the governance process at our follow up inspection and the provider was working to further develop these
- The provider did not have an agreed, shared and comprehensive definition of which incidents to report. There was no agreed policy which defined incidents, how to investigate them or communicate outcomes. As a result, they did not have fully developed systems to record, analyse or learn from the complete range of incidents, or a process for reporting them. We found actions had been taken to address these at our follow up inspection.
- There was no programme of clinical and internal audit in place in order to monitor quality and systems to identify where action should be taken. The registered manager was unable to provide evidence of any audits. At our follow up inspection, we found that there were plans to carry out some audits, such as hand hygiene. The provider was further considering what other useful audits they could carry out.
- The provider did not ensure that all staff underwent appropriate checks as required by schedule 3 of the HSCA 2008 (regulated activities) regulation 2014. Their recruitment procedures were ineffective, for example, we looked at the file for the new receptionist and found that there were no references in her file. We asked the registered manager and clinic manager about this who told us they had been applied for but not come through yet. We saw at our follow up inspection this had improved and verbal references had been received with written references in the post.
- There were some policies and procedures in place to provide guidance to staff, however these were not fully implemented. They did not suit the provider being delivered for example referred to other organisations, residents or processes that were not in place at this provider. We found this had improved at our follow up inspection, we found up-to-date policies and procedures, which staff were knowledgeable about and knew where to access the documents. These policies included, safeguarding, infection prevention control, duty of candour and chaperone. At the time of this inspection the provider was ensuring all policies were up-to-date, suit the service being delivered and were fully implemented by staff.
- All staff were covered by the providers indemnity and medical liability insurance which was renewed annually.

Diagnostic imaging

Managing risks, issues and performance

The provider did not have systems to identify risks, plan to eliminate or reduce them, and cope with both the expected and unexpected.

- The provider did not have robust systems to monitor, analyse or take action on safety, quality, performance or risk. There were no robust arrangements for identifying, recording and managing risks and mitigating actions or contingency plans. Risks we identified during our inspection such as lack of safeguarding and mandatory training for staff and the management of clinical waste had not been identified by the provider and therefore could not be mitigated. The registered manager told us of a few risks they had considered to be present but had not acted on these to mitigate them. We found improvements in the risk management process at our follow up inspection and the provider was working to further develop these, for example, they had introduced morning huddle meetings, which included all staff on shift, and gave protected time to discuss the appointments booked in, any updates, learning or concerns. The provider informed they will minute the morning huddles to monitor the quality of the service and identify any risks or challenges in the day to day of the provider.
- There was no system in place to ensure staff had received essential mandatory training such as safeguarding and first aid. Whilst the registered manager told us they had carried out essential training in the last year, we were not provided with evidence of this.
- The provider did not have business continuity plans in place.

Managing information

The provider did not collect analyse, managed or used information well to support its activities

- The provider did not collect, analyse, or manage information well to support all its activities. There was no audit process and the provider could not clearly tell us how many scans they had performed in the last year.

Engagement

The provider provided a platform for women to leave feedback on the provider, however we did not see this used to improve providers.

- The provider gathered feedback from women and families through online review sites and social media pages. The website included details on how women could leave feedback. The website also showed stories of women's experience of using the provider and their pregnancy. Women could also leave feedback on comments cards We did not see how feedback was used to improve the provider.
- As the two of the three-staff employed were new there had been no opportunity to meet as a team, however the clinic manager told us they were planning to introduce a daily huddle to discuss key issues and concerns as well as discussing provider delivery.

Learning, continuous improvement and innovation

The provider did not improve providers by learning from when things went well or wrong as they did not have process in place to support this.

- We found no systems and processes in place to learn, continuously improve or innovate at this inspection.
- The newly appointed clinic manager had created a plan to cover some of the key clinic concerns we identified, however some issues had not been identified.

Outstanding practice and areas for improvement

Areas for improvement

Action the provider MUST take to improve

- The provider must ensure mandatory training in key skills is provided to staff.
- The provider must ensure staff understand how to protect women and people attending the clinic from abuse.
- The provider must ensure staff have the appropriate level of training on how to recognise and report abuse and know what their responsibilities were in relation to safeguarding.
- The provider must ensure they implement effective control measures to prevent the spread of infection.
- The provider must operate an effective system to ensure that equipment is in date and suitable for use.
- The provider must ensure scan equipment is checked prior to use and this is recorded and audited.
- The provider must ensure patients records are suitably stored at all times.
- The provider must ensure there is an incident reporting process in place and that this operates effectively.
- The provider must ensure incidents are recorded, investigated and any lessons learned shared.
- The provider must ensure there is a duty of candour policy and that the duty of candour requirements is met (when applicable).
- The provider must ensure staff are aware of their responsibilities in relation to duty of candour and receive suitable training.
- The provider must ensure there is an effective governance process in place.
- The provider must ensure there is a system to identify risks, plan to eliminate or reduce them, and cope with both the expected and unexpected.
- The provider must ensure there is a programme of clinical and internal audit in order to monitor quality and systems to identify where action should be taken.
- The provider must ensure staff undergo appropriate checks as required by schedule 3 of the HSCA 2008 (regulated activities) regulation 2014.

This section is primarily information for the provider

Requirement notices

Action we have told the provider to take

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

Regulated activity	Regulation
Diagnostic and screening procedures	Regulation 12 HSCA (RA) Regulations 2014 Safe care and treatment **Regulation 12 HSCA 2008 (Regulated Activities) Regulations 2014 Safe care and treatment**

Regulated activity	Regulation
Diagnostic and screening procedures	Regulation 13 HSCA (RA) Regulations 2014 Safeguarding service users from abuse and improper treatment **Regulation 13 HSCA 2008 (Regulated Activities) Regulations 2014 Safeguarding service users from abuse and improper treatment**

Regulated activity	Regulation
Diagnostic and screening procedures	Regulation 17 HSCA (RA) Regulations 2014 Good governance **Regulation 17 HSCA 2008 (Regulated Activities) Regulations 2014 Good governance**

Regulated activity	Regulation
Diagnostic and screening procedures	Regulation 18 HSCA (RA) Regulations 2014 Staffing **Regulation 18 HSCA 2008 (Regulated Activities) Regulations 2014 Staffing**

This section is primarily information for the provider

Requirement notices

Regulated activity	Regulation
Diagnostic and screening procedures	Regulation 19 HSCA (RA) Regulations 2014 Fit and proper persons employed **Regulation 19 HSCA 2008 (Regulated Activities) Regulations 2014 Fit and proper persons employed**

Regulated activity	Regulation
Diagnostic and screening procedures	Regulation 20 HSCA (RA) Regulations 2014 Duty of candour **Regulation 20 HSCA 2008 (Regulated Activities) Regulations 2014 Duty of candour**

This section is primarily information for the provider

Enforcement actions

Action we have told the provider to take

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

Regulated activity	Regulation
Diagnostic and screening procedures	Section 31 HSCA Urgent procedure for suspension, variation etc. Section 31 urgent suspension of registration for period of six weeks.