

Beard Mill Clinic

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? | Outstanding | 公 |
| Are services responsive? | Good | |
| Are services well-led? | Good | |

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

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

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

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

Letter from the Chief Inspector of Hospitals

Beard Mill Clinic is operated by Dr Victoria Heath. The service provides antenatal ultrasound screening for pregnant women, from 6 weeks up to full term. It is located in rural setting to the west of Oxford. The provider, Dr Victoria Heath, carries out all the ultrasound screening herself and the services are offered to privately funded patients only.

The premises have been designed specifically for this purpose, and the facilities are all on the ground floor. There is a large waiting room and reception desk, the ultrasound room and a disabled toilet. In addition, there is a staff kitchen and store room, with an area for records storage on an upper floor. There is extensive adjacent parking.

Beard Mill Clinic is registered to provide the regulated activity diagnostic and screening procedures.

We inspected this service using our comprehensive inspection methodology. We carried out the short-notice (48 hours) announced inspection on 30 January 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.

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

We have not rated this service before and we rated this service as **Good** overall.

We found good practice in relation to:

- The provider, Dr Victoria Health, had the skills, training and experience to keep people safe from avoidable harm and provided the right care and treatment. She ensured she was competent for her role and had the right skills and abilities to run the clinic service to benefit patients, working well with specialist services and GPs. She checked staff in the contracted reception service had the right skills and training to provide the right care.
- The service controlled infection risk well. The premises were kept clean and the provider used control measures to prevent the spread of infection.
- The clinic had suitable premises and equipment and the provider looked after them well.
- The provider reviewed and updated risk assessments for each patient, using a tailored patient questionnaire and kept detailed records of patients' care and treatment. The service collected, analysed, managed and used information well to support all its activities, using secure electronic systems with security safeguards. The provider sought patients' consent for a scan and for holding personal information.
- The provider had systems to manage patient safety incidents.
- The service provided care based on national guidance and evidence of its effectiveness and monitored the effectiveness of care. The provider used these results to improve practices.
- The service offered flexible appointment times so people could access the service when they needed it.
- The provider cared for patients with compassion and offered emotional support to reassure them and minimise any distress. The service took account of patients' individual needs and put them at the heart of services. Patient feedback was consistently positive about the provider's reassurance, kindness and support, and the provider had good links to counselling services.
- The provider involved patients and those close to them in decisions about their care and treatment.

Summary of findings

- The service was planned and provided in a way that met the needs of people who used the service.
- The service treated concerns and complaints seriously, investigated them and learned lessons from the results.
- The service had a vision for what it wanted to achieve and reviewed this based on patient feedback and local engagements with services. The provider promoted a positive culture combining high quality services and a relaxing, welcoming environment.
- The provider had a systematic approach to improving the quality of service
- The service had identified some risks and put in plans to eliminate or reduce them.
- The service was committed to improving services by learning from when things went well or wrong, promoting training, research and innovation.

We found outstanding practice

• The provider had a range of approaches to assess their quality of practice. These included reviewing results against benchmarked data, evaluating patient feedback against fetal measurements and obtaining peer reviews on their own performance. This demonstrated a strong commitment to providing high quality patient care.

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

- The service had not identified and reviewed new hazards to mitigate their risks.
- The provider had not risk assessed all the non-clinical cleaning materials used on the premises, in line with the Control of Substances Hazardous to health (COSHH) regulations.
- The provider had not referenced details on the types of incidents that must be reported to other agencies, such as the CQC, in the incident reporting policy.

Nigel Acheson

Deputy Chief Inspector of Hospitals London and South

Summary of findings

Our judgements about each of the main services

| Service | Rating | Summary of each main service |
|-----------------------|--------|---|
| Diagnostic imaging | Good | This was a limited company run by an individual practitioner. The clinic provided a diagnostic imaging service for pregnant women. As a sole practitioner, the provider, Dr Victoria Heath, did not employ clinical staff. We rated this service as good because it was safe, responsive and well led. We rated caring as outstanding. We do not rate effective for this type of service. |

Summary of findings

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Good

Beard Mill Clinic

Services we looked at Diagnostic imaging

Background to Beard Mill Clinic

Beard Mill Clinic is operated by Dr Victoria Heath. This private clinic is registered to provide diagnostic and screening procedures and provides obstetric ultrasound scans for pregnant women. Located in the countryside

near Witney, Oxfordshire, it opened in 2007 and primarily serves the communities of Oxfordshire, Swindon and Reading although it also accepts patients from outside this area.

This inspection took place on 30 January 2019.

Our inspection team

The team that inspected the service comprised a CQC lead inspector. The inspection team was overseen by Amanda Williams, Interim Head of Hospital Inspection for South Central and South London.

Information about Beard Mill Clinic

During the inspection, we reviewed the premises, equipment and documentation. We spoke with the owner, Dr Victoria Heath and with four patients and their relatives. We observed the care provided for two patients at the clinic and we reviewed four sets of patient records.

There were no special reviews or investigations of the service ongoing by the CQC at any time during the 12 months before this inspection and this was the second inspection of the service since registration with CQC. The report from the previous inspection was published in February 2103 and showed the service met the five standards of safety and quality it was inspected against.

Annual activity (November 2017 to November 2018)

- All patients self-payed and the clinic did not provide NHS-funded scanning services.
- The provider, Dr Victoria Heath, did not employ any staff and undertook all ultrasound imaging herself. She had a contract for a telephone receptionist service.

Track record on safety

- No never events, clinical incidents or serious injuries
- No incidences of hospital acquired infections
- No complaints

No other services used the premises.

Services accredited by a national body:

• The service had no accreditations.

Services provided at the hospital under service level agreement:

- Telephone reception services
- Clinical waste removal
- General cleaning of the premises
- Maintenance of ultrasound equipment
- Fire equipment checks
- Water safety checks

The five questions we ask about services and what we found

We always ask the following five questions of services.

Are services safe?

This was the first time this service has been rated. We rated it as **Good** because:

- The provider, Dr Victoria Health, as sole practitioner, had completed all mandatory training, including training in safeguarding adults and children.
- The provider understood how to protect patients from abuse and had completed training on how to recognise and report abuse so they knew how to apply it.
- The service controlled infection risk well. The premises were kept clean and the provider used control measures to prevent the spread of infection.
- The clinic had suitable premises and equipment and the provider looked after them well. The premises had been designed to a high standard, to meet the needs of patients, and there were systems to ensure the equipment was safe.
- The provider reviewed and updated risk assessments for each patient, using a tailored patient questionnaire. They discussed patients' wishes and worries to ensure they helped answer they concerns.
- The clinic had a contract for reception services and the provider ensured the remote receptionists had the skills and training to keep people safe and to provide the right care. The provider trained the cleaner and monitored their practices.
- The provider kept detailed records of patients' care and treatment. The records were up-to-date, of high quality and easily available
- The provider had systems to manage patient safety incidents.

However

• The general cleaning chemicals were not included in the clinic's Control of Substances Hazardous to health (COSHH) risk assessments.

Are services effective?

We do not rate effective for this type of service.

• The service provided care and treatment based on national guidance and evidence of its effectiveness. This included the use of non-invasive prenatal testing and growth scans.

Good

- The provider monitored the effectiveness of care and used the findings to improve them. They undertook audits and reviewed feedback from patients to retrospectively evaluate their assessments.
- As sole practitioner, the provider maintained competency through working regularly at an NHS trust, having a mentor and annual appraisals, and attending relevant conferences.
- The clinic had good links with local NHS services, including the fetal medicine units and early pregnancy units in hospitals, and with local GPs.
- The provider explained procedures to patients and accepted their verbal consent. The clinic did not carry out scans on children.

Are services caring?

This was the first time this service has been rated. We rated it as **Outstanding** because:

- The provider offered compassionate care, and there was a person-centred culture. The provider promoted a caring, professional approach to the services offered.
- Patients were respected and valued as individuals and were empowered as partners in their care.
- The provider ensured patients' questions were answered in full, and they provided reasons for the reassurance they provided. The appointments were planned to give the provider time to explain findings in detail and make suggestions for future care arrangements.
- The clinic had good links to counselling services including a national charity that supports people receiving potentially distressing news about their unborn child.
- Patients provided consistently good feedback about the clinic, including about the attitude of the provider. Feedback responses were entirely positive and very complimentary.

Are services responsive?

This was the first time this service has been rated. We rated it as **Good** because:

• The service was planned and provided in a way that met the needs of people using the service. Beard Mill Clinic had been designed specifically to meet the provider's brief for high quality premises. The website was clear and informative, and included prices.

Outstanding

Good

- The service took account of patients' individual needs and put them at the heart of services. Patients said appointments were easy to make and there was ample parking. There was disabled access and the service could meet the needs of larger women.
- The provider waived charges for repeat scans under specific circumstances.
- People could access the service when they needed it. The clinic offered patients appointments from Monday to Friday between 8am and 5pm. It was not at full capacity and the provider could often offer patients a same-day or next-day appointment. The provider aimed to make onward referrals before patients left the clinic. During absences, the provider arranged for patients to be offered an alternative private clinic nearby.
- The service had not received any complaints in the past year. The provider, Dr Victoria Heath, was responsible for managing complaints and had systems to manage and respond to complaints or concerns if raised.

Are services well-led?

This was the first time this service has been rated. We rated it as **Good** because:

- The provider, Dr Victoria Heath, had the right skills and abilities to run the service. As the sole practitioner, she took responsibility for all aspects of the service, including governance, clinical management, health and safety and quality. They provided a high level of clinical leadership, having trained in obstetrics gynaecology, neonatology and fetal medicine and undertaken research into screening programmes.
- The service had a vision for what it wanted to achieve and reviewed this based on patient feedback and local engagements with services. The service was set up to offer ultrasound screening and advice in pregnancy and its aims were to supplement, and not replace, the antenatal care provided by the NHS.
- The provider had a systematic approach to improving the quality of service. Clinical excellence was the focus of the clinic's approach to delivering high-quality patient care and the provider had set up systems for monitoring outcomes for patients.
- The provider had undertaken risk assessments related to key risks associated with the service. There were systems to manage known, existing hazards, such as those relating to clinical cleaning products and the proximity to the river and the internal glass bridge over the river.

Good

- The service collected, analysed, managed and used information well to support all its activities, using secure electronic systems with security safeguards. The provider's data protection policy reflected the General Data Protection Regulations (GDPR) and the clinic was registered with the Information Commissioner's Office. Patients to complete the clinic's patient registration forms and signed a personal data consent form. All electronic systems were password protected, and the provider filed patient records using a unique identifier to support confidentiality.
- The service engaged well with patients to plan and manage appropriate services, and collaborated with partner organisations effectively. The provider sought patient feedback directly, via outcome forms included with patient reports, and also from annual patient surveys. They also asked for feedback from colleagues.
- The service was committed to improving services by learning from when things went well or wrong, promoting training, research and innovation. The provider maintained a folder showing the additional courses they had attended relating as part of her continuing professional development. They also maintained their honorary contract with a London NHS trust to keep up to date with skills.

However

- The provider had not risk assessed being a lone-worker at Beard Mill Clinic.
- The types of incidents that must be reported to other agencies, such as the CQC, were not included in the incident reporting policy.

Detailed findings from this inspection

Overview of ratings

Our ratings for this location are:



| Safe | Good | |
|------------|-------------|---|
| Effective | | |
| Caring | Outstanding | ☆ |
| Responsive | Good | |
| Well-led | Good | |

Are diagnostic imaging services safe?

Good

Mandatory training

The provider completed mandatory training in key skills

- The provider, Dr Victoria Heath, was the only staff member at the clinic. She had completed statutory and mandatory training in a range of different topics, including equality and diversity, safeguarding adults and children, preventing radicalisation, data security awareness, fire safety, health safety and welfare, infection prevention and control, moving and handling, resuscitation (including paediatric and new-born) and CPR.
- The frequency of updates was one or two years, except for () which was three years. The provider was up to date with all her mandatory training.

Safeguarding

The provider understood how to protect patients from abuse and had completed training on how to recognise and report abuse so they knew how to apply it.

- The provider had completed level 2 safeguarding training in both adults and children. This is the minimum level of training required for clinical staff who have contact with children, young people, parents and carers and vulnerable older people.
- The clinic's safeguarding policy and procedures outlined the steps the provider would take if they

suspected a patient was at risk of abuse, or their unborn child. The policy included guidance on who to contact in such circumstances, and listed the contact details for the local adult and children's safeguarding boards.

- The provider also had access to safeguarding advice from an NHS trust where she had an honorary contract.
- The provider had completed a course on recognising and supporting women subjected to female genital mutilation.
- Dr Victoria Heath had not had cause to raise a safeguarding alert since opening the clinic, but had experience of safeguarding referrals from working in an NHS hospital.

Cleanliness, infection control and hygiene

The service controlled infection risk well. The premises were kept clean and the provider used control measures to prevent the spread of infection.

- The clinic's provider was the infection control lead and had completed training in infection prevention and control. There had been no hospital acquired infections in the 12 months prior to the inspection.
- All aspects of the premises appeared visually clean and tidy. There was a hand wash basin in the scanning room, and toilet facilities accessed from the waiting room.
- The clinic had cleaning protocols and checklists to provide assurance that cleaning was completed effectively. There was a cleaning protocol outlining the

tasks required and detailing the spillage protocol. We saw completed weekly cleaning records that showed the waiting room, scanning room, kitchen and toilet had been cleaned.

- There was a protocol to maintain ultrasound probe hygiene. The provider cleaned the ultrasound equipment and used cleaning wipes recommended by the manufacturer for surface disinfection and cleaning. The probe used for abdominal scans were cleaned between each patient and at the end of the day with a high-level disinfectant. They were washed in hot water with soap each week. The provider used disposable sterile probe covers when carrying out internal scans and there was sufficient personal protective equipment such as latex and non-latex gloves.
- We observed the provider washed her hands between patient contacts and changed the disposable paper covering on the couch after each patient.
- There was a correctly assembled sharps box used for the safe disposal of needles. The provider had a contract for the removal of clinical waste, that had been renewed in August 2018.
- There was a policy for blood borne viruses (BBV) to protect staff from against the risk of acquiring a BBV infection, for example from a sharps injury.

Environment and equipment

The clinic had suitable premises and equipment and the provider looked after them well.

- The provider had a contract for annual servicing of the ultrasound equipment. We saw the most recent service report dated January 2019.
- The ultrasound equipment carried out a self-checking procedure at start up, to show it was working safely. The application specialist and provider had initially set up the default settings, to provide the best quality images.
- The clinic's health and safety prevention and control policy (updated November 2018) included the control of substances hazardous to health (COSHH) guidelines and identified the substances used at the clinic for ultrasound procedures and the safety precautions in place. It did not include household cleaning products.

- There were records that demonstrated annual water testing, with the latest water sampling report dated September 2018. The provider had not been required to take any actions.
- We saw a suitable waste management policy and a valid contract with a new clinical waste company.
- The provider did not have resuscitation equipment, but maintained a first aid box which was replaced before the contents reached their expiry dates, or refilled if necessary. Dr Victoria Heath had assessed the risks associated with the service and of her patient group and had concluded the clinic did not require resuscitation equipment.
- There was evidence of regular servicing of the fire extinguishers and security lighting.

Assessing and responding to patient risk

The provider reviewed and updated risk assessments for each patient, using a tailored patient questionnaire.

- The provider kept clear records of patients' risk assessments, to ensure the right person, had the right ultrasound scan at the right time. Patients who attended for an ultrasound scan completed a form about themselves and their pregnancy, and any previous pregnancies. This included their name, date of birth, address, phone numbers and email addresses. It also included partner details. The form asked for the GP contacts, details of previous pregnancies and outcomes as well as the details of the current pregnancy.
- The provider reviewed these details with patients and checked their understanding of what scan they wanted and any concerns. She asked patients further information about previous pregnancies and births, and their current expectations and concerns, to help guide the plan of care and procedure.
- The provider had instructed the contracted receptionist staff on how to answer phone calls from patients. These instructions included politely asking patients about their pregnancy dates and what information the patient wanted, and giving them an indication of the type of appointment that might be suitable. The receptionists emailed new appointment

details to the provider for them to check whether the booking was appropriate or if they needed to contact the patient for more information. The receptionists had access to the provider's booking diary.

- The provider explained how they set the ultrasound equipment to work within safe limits based on the thermal and mechanical measures of the high-frequency sound waves, used to create the images. The equipment was set up to be significantly below the upper limits of the thermal and mechanical safety margins, and reports included these settings for reference. Higher frequency settings were used for Doppler ultrasound, to observe blood flow, or for larger patients.
- The provider reviewed the image results with the patients and their relative/friend immediately after the scan, which we observed during the inspection. The provider was careful to prompt patients to continue to attend NHS antenatal appointments, including screening tests, so they maintained their NHS links for ongoing antenatal and postnatal care. She also asked permission to share reports with the patient's GP so they were aware of the findings.
- If a scan indicated potential fetal anomalies, the provider had protocols with the three fetal medicine units in nearby NHS trusts, and made same-day referrals. For patients living outside these areas, the provider emailed the relevant NHS trust screening coordinators or fetal medicine units and followed these up to ensure patients were seen for further care. The provider discussed their findings with the NHS staff and provided copies of scans and reports.
- We saw a record for a patient where the provider had assessed a higher than normal risk of Down's Syndrome from the non-invasive prenatal test (NIPT). They had phoned the patient with the results and explained the results carefully so the patient understood the risks indicated by the results. She immediately referred the patient to their nearest NHS fetal medicine unit for further care.
- We reviewed another report that showed the provider had given a clear summary of findings and sought a second opinion when the ultrasound scan indicated an anomaly.

- The service had protocols for transvaginal scans and we observed that these were only carried out if assessed as necessary.
- The provider was trained in basic life support. If a patient collapsed in the clinic, the provider would support the patient and call emergency services for an ambulance.

Staffing

The provider was a sole practitioner, with a contracted receptionist agency service. The provider checked the agency's staff had the right skills and training provide the right care.

- The provider visited the reception agency, trained the receptionist staff and provided them with a handbook to refer to. The handbook emphasised the clinic values and summarised the key roles of receptionists. These included advising patients to contact their own GP or emergency services if they needed urgent care. All agency staff had signed confidentiality agreements with Beard Mill Clinic.
- The provider had not assessed the risks of lone working, since changing from having an on-site receptionist to using contracted remote services.

Records

The provider kept detailed records of patients' care and treatment.

- The clinic created comprehensive records of patients' care. They were clear and compiled contemporaneously. They showed the patient journey, for example when and how their referral was made, appointment details, scan details and commentary. Each patient had a unique patient identifying number and the provider kept electronic and hard-copy files.
- Access to electronic records and the ultrasound machine was password protected and there were no other operatives on the premises who shared the equipment. The receptionists had password protected access to the clinic diary only.
- The clinic's information security policy covered arrangements for the collection and storage of paper documents, data held on the ultrasound machine,

data stored on the software package, emails and financial data. The policy included document retention timescales. Hard-copy reports were kept in locked cupboards within the clinic storage areas.

- The provider shared results with GPs by first class post, and referrals with hospitals by telephone and/or email if there were anomalies or concerns to report.
- Feedback from health professional colleagues showed they considered the provider kept records well. Results from a survey in February 2018 showed 14 colleagues (health professionals the provider liaised with in relation to patient care) rated the provider as very good (11) or good (1) for medical record keeping and remainder reported 'don't know'.

Medicines

The provider did not prescribe, store or administer medicines.

Incidents

The provider had systems to manage patient safety incidents.

- The provider said they were committed to honesty, learning and improvement and had put in place systems to review clinical performance including those relating to incidents and near misses.
- There had been no incidents in the past 12 months. The provider outlined previous examples of no-harm incidents, where there had been learning, and explained the changes made in response.
- We saw the template used for recording incidents and near misses.
- The provider was aware of the duty of candour and its requirement to be open and honest with patients if the clinical services caused them harm. The provider had never had to apply this duty.

Are diagnostic imaging services effective?

Evidence-based care and treatment

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

- The provider had protocols for the services offered. These included scans for viability, nuchal translucency (a screen for specific abnormalities), anomaly, growth and gender. The clinic also offered non-interventional prenatal testing (NIPT), which is a blood test to screen for specific chromosomal disorders, 3D/4D scans and cervical length measurements.
- The protocols stated the best times to carry out each procedure, the purpose, method and likely outcomes and explanations to give to patients.
- For example, the protocol for the NIPT, stated the provider only carried out this procedure alongside a detailed scan, such as a nuchal scan if the gestation was less than 14 weeks, or an ultrasound scan for later gestations. The protocol included when NIPT would be appropriate or inappropriate, and reasons for carrying out this test in combination with a scan, to inform care planning. The protocol included ensuring patients were fully aware of key aspects of the NIPT; it was not a diagnostic test and had the potential for false positives and false negatives and about 3% initial tests failed first time. It outlined how the provider would tell patients the results, and if the results indicated an abnormality, how the provider would initiate contact with the fetal medicine unit (FMU). The FMUs are regional NHS services specialising in complications that may arise in unborn babies.
- The provider was aware of the 2017 report published by Nuffield Council on Bioethics about the ethical issues surrounding NIPT and this was reflected in the clinic's policy and procedure.
- The provider had a policy and procedure on referral for fetal abnormality. If they detected or suspected a fetal abnormality, the protocol outlined how these findings should be communicated and reported. The provider aimed to make all onward referrals before the patient left the clinic, to support them and provide reassurance.
- For example, if the patient was booked to have her baby at a local NHS trust, the provider could make direct referrals to the FMU in the local NHS trust, and the contact details were in the policy. If the patient

was from a different hospital, then the provider contacted the screening coordinator at that hospital to discuss the findings with them and arrange an onward referral.

• The provider had arrangements to contact the early pregnancy unit or the maternity assessment unit/ labour ward if they suspected or confirmed a miscarriage.

Nutrition and hydration

The service did not routinely offer patients or their relatives drinks, but could provide these if necessary or requested.

- There was a small staff kitchen on site where the provider could prepare hot or cold drinks.
- There was guidance on the Beard Mill Clinic website, under frequently asked questions, that advised patients they did not need to have a full bladder for their scan.

Pain relief

This type of service did not need to provide pain relief routinely.

• The provider did not offer patients pain relief as part of the services offered.

Patient outcomes

The provider monitored the effectiveness of care and used their findings to improve outcomes for patients.

- The provider assessed the accuracy of their screening tests, by asking for feedback from patients to check if she had missed an antenatal diagnosis. They reviewed these results monthly and also at their annual appraisal arranged through the NHS trust where she also worked under an honorary contract. There had been no such omissions in the past 12 months.
- The provider had an audit schedule to review outcomes and they presented the results annually at their appraisal. These included audits of biometric data, referrals to the fetal medicine unit, referrals for invasive testing and any missed diagnoses.
- The provider had an online system to carry out automatic first trimester audits of all nuchal

translucency scans, and compare them with results internationally. These should show a normal distribution curve. The provider's results showed they conformed to the normal distribution.

- The Fetal Medicine Foundation audited the clinic's first trimester screening results annually. This involved plotting the nuchal translucency measurements against the normal range, from their own database of about 100,000 cases, and analysing the distribution of the measurements. The audit also involved a review of images and measurements of bones and blood flow. The Foundation approved the results of the last audit which meant the provider was on the list of certified sonographers to risk assess chromosomal abnormalities.
- When the provider identified any unusual or abnormal images that required further referral to NHS specialists, they always followed up the outcomes with the patients. This was to both offer support and to assess the accuracy of the diagnoses.
- The provider audited biometric data, such as femur length, head circumference and diameter, and abdominal circumference to make sure these were within expected limits. They audited this data quarterly and presented results at their annual appraisal, to demonstrate accuracy in estimating fetal weight and gestational age.
- The provider also monitored referrals for invasive testing and referrals to the fetal medicine unit, and their audit results showed they made appropriate referrals.
- Patients were invited to email the provider after their appointment, if they had any queries. They were also asked to return an outcome form, after the birth of their baby. This helped the provider monitor the accuracy of their reports.
- The provider carried out patient feedback audits and addressed any suggestions or improvements. One improvement suggested was to display signage to explain why there was no one in reception sometimes when a patient arrived. The provider had since created a sign explaining they might not be available in reception, if they were with a patient in the scanning room.

Competent staff

The staff were competent for their roles.

- The provider, Dr Victoria Heath, had over 20 years of experience in fetal medicine and was an associate member of the Royal College of Obstetricians and Gynaecologists. She was a research fellow for a fetal medicine unit at an NHS trust and she specialised in fetal screening in private and NHS organisations. She had completed the Royal College of Radiologists' diploma in advance obstetric ultrasound. Earlier in her career she had been involved in training staff in NHS units on how to screen women in their first three months of pregnancy.
- Having set up her own private obstetric ultrasound clinic, she continued to provide NHS sessions in a fetal medicine unit in London, where she held an honorary contract. This arrangement enabled her to maintain links with a wider team of specialists for discussion, review of cases and training. In 2018, for example, the provider undertook clinical sessions approximately once a month. Dr Victoria Heath also had regular meetings with a fetal medicine specialist, where she had previously been employed, who also acted as her mentor.
- The provider ensured they kept updated in obstetric ultrasound in pregnancy. In the previous six months they had attended courses in 'advances in fetal medicine', 'an update on infections during pregnancy', 'effective prenatal screening of congenital heart disease' and a 'non-invasive prenatal screening' seminar. They also read the national screening committee (NSC) blogs and articles in The Obstetrician and Gynaecologist. We saw the provider maintained a log of relevant journals and reports they had read for her professional development.
- Dr Victoria Heath received annual appraisals from a lead obstetrician at the NHS trust where she also worked. Her last appraisal report from March 2018 stated she kept up to date with progress in fetal medicine and any training, and summarised future goals and agreed learning plans.
- The provider had completed professional revalidation in 2015 and their next revalidation was due in July 2020.

Multidisciplinary working

The provider worked with specialist services and GPs to benefit patients.

- The provider had strong links with local GPs and screening coordinators at local hospitals. They also had an effective working relationship with the fetal medicine unit and the early pregnancy unit at the local NHS trust. For example, the NHS trust took direct referrals from the clinic if the provider identified an abnormality risk.
- A survey of colleagues in February 2018 showed very positive feedback from health professionals who referred patients to the clinic and those who received the provider's referrals in hospitals. For example, an antenatal screening health professional said Dr Heath kept them well informed with updates on mutual patients. Another said they often recommended patients to Dr Heath, commenting on her clear and comprehensive communication with primary care colleagues.
- The provider commented the screening co-ordinators at three of the local hospitals and staff at both the local fetal medicine unit and early pregnancy unit recommended that patients contact Beard Mill Clinic if they themselves were unable to help. They also always took direct referrals from the clinic if the provider detected a suspected abnormality, as they had confidence in the provider's judgements.
- The provider contracted and approved a telephone reception service, staffed by receptionists, to manage all enquiries. As a team, they communicated well and ensured they responded to patients promptly.

Seven-day services

The service was not established to offer a seven-day or emergency service. It offered flexible appointment times or an alternative provider if necessary.

• The service was operational Monday to Friday, 8am until 5pm, but the provider could sometimes extend these hours to support specific patient requests.

• The provider also referred patients to another, nearby, private pregnancy scanning service if they could not accommodate appointment requests, for example outside normal working hours.

Health promotion

The provider offered some advice on healthy pregnancy to patients if they requested it, but this was not part of the services offered by the clinic.

Consent and Mental Capacity Act

The provider sought patients' consent for a scan and for holding personal information.

- The provider understood their responsibility to gain consent from pregnant women attending the clinic for ultrasound scanning services. The provider explained the procedure and patients had the opportunity to withdraw if they wished. The provider always confirmed with patients what they wanted from the scan, the limitations of the scan and how long the procedure would take.
- Patients presenting for a scan did not need to sign consent for this, but they completed an assessment form about themselves and their pregnancy.
- The assessment form included a section for patients to sign consent to Beard Mill Clinic's management of personal data, and this included sharing information with their GP.
- After their procedure, the provider checked patients understood their consent to share results with their GP.
- The provider did not carry out scans on children. If a young person, over 16 years of age, presented for a scan, the provider said they would assess if they were competent to make decisions about their pregnancy, and encourage them to attend with a partner or parent. In practice, the provider had not received referrals from women under 18 years of age.

Are diagnostic imaging services caring?

Outstanding

Compassionate care

The provider cared for patients with compassion.

- Beard Mill Clinic received consistently positive praise. Patients we spoke with said they appreciated the extra time for the appointment and the provider's friendly, caring approach. One person said they had specifically chosen to have their ultrasound scan carried out here because of the positive feedback and the reputation of the provider. Another said they had been recommended by a friend.
- The provider carried out annual surveys of patients' opinions. The most recent survey, undertaken over a two-week period in January 2019, received 27 responses. Almost all patients gave the clinic a rating of 10/10, and answered 'attitude of staff' with descriptions such as caring, sensitive, diligent and professional. Feedback included 'cannot fault it', 'would certainly recommend' and 'I felt valued as an individual'.
- Results from the previous patient survey, in February 2018, showed all feedback was at the highest level; 'very good'.
- The provider used their first name with patients, and there was evidence of a very personal yet professional service. As the sole provider of care, patients who had used the clinic on previous occasions built up a trust and friendship with the provider. Dr Victoria Heath asked patients to let her know about the baby after the birth, and we saw a collection of cards she had received.
- The provider ensured patients were treated with respect and dignity. For example, the provider knew the names of the patients arriving, and had checked any previous obstetric or medical history she already had on file. For the scan, they offered patients paper towels and pre-warmed the gel to make the experience more comfortable.
- The provider explained how she had tailored the service to promote compassion and care. For example, they had explored offering a wider range of services but recognised this could make it difficult to adequately support a distressed patient.
- Appointment times were arranged to minimise overlap and waiting times for patients, to promote privacy.

• The service had chaperone guidelines. As a sole practitioner at the service, the guidelines explained the provider would not be able to offer a chaperone without warning. If requested in advance, the provider could offer a suitable external healthcare professional to attend or they could postpone the appointment to a time when the patient could bring someone with them.

Emotional support

The provider offered emotional support to patients to reassure them and minimise any distress.

- The provider talked with patients before the scan to check what they wanted from the appointment and to find out if they had any worries about their pregnancy. We observed the provider gave specific reassurance during scans on issues where patients had concerns, for example on estimated birth dates or growth rates. Dr Victoria Heath described what she saw on the scan in positive terms, such as 'nice, regular heart beat' and 'nice and normal', which patients found reassuring.
- There was consistent feedback in the patient surveys that the provider offered reassurance. One comment was, 'I can now relax and enjoy my pregnancy'. We observed a patient having their scan with their consent, and she commented 'I can now sigh a sigh of relief' after the provider had explained the measurements and observations identified through the scan.
- We observed the provider answered patients' questions about their specific concerns clearly and in detail. They explained the benefits and risks of different procedures and the best times to have them, and in doing so guided people against having procedures at inappropriate stages in their pregnancy.
- The provider explained they was sensitive when enquiring why patients did not arrive for their appointments, in case they had experienced a miscarriage.
- If the provider had to give a patient bad news, they gave patients time to come to terms with the findings and plenty of opportunity to ask questions. They would be afforded privacy, and not asked to wait in

the waiting room if other patients were waiting, but stay in the ultrasound room. This approach was formalised in the clinic's policy for referral for fetal abnormality.

- Feedback also highlighted people felt valued and treated as individuals by this service. We saw comments such as 'Thank you so much for our scan this week, and for being so thorough. Even though you found something not entirely normal - you were extremely reassuring - and we felt grateful that you had picked it up for us..... We really are so grateful that you not only spotted this issue, but were so reassuring in your manner and your explanation. We feel as if we've been in very safe hands, which helps enormously', 'It's been a really rocky road but I wanted to let you know and thank you for supporting us with additional scans and knowledge which helped empower us to ask the right questions.We are grateful for the support you gave us during a scary time in my pregnancy', and 'Thanks so much for your advice and support during all our scans'.
- The provider had attended a counselling course given by a national charity that supported women with antenatal scans, and was able to counsel patients if they reported distressing news about their pregnancy. They also referred patients for longer-term counselling or to local counsellor for face to face support and counselling.
- From their links with a charity the provider offered to scan patients referred to her by this charity, free of charge.

Understanding and involvement of patients and those close to them

The provider involved patients and those close to them in decisions about their care and treatment.

- Feedback from patients showed they fully understood the procedures they had received. We saw comments on survey responses such as, 'Goes the extra mile to explain findings on the scan', '[The provider] always fully explains what she does and why' and 'All my questions were answered'.
- We observed patients and their relatives felt comfortable asking questions and the provider gave them full, informed answers. For example, when asked

about the risks or implications of having taken antibiotics, they answered referring to National Institute for Health and Care Excellent (NICE) guidance and research findings.

- Before the scan, the provider asked parents if they wanted to know the gender of the baby. If they didn't, they advised them they would ask them to look away from the screen when the baby's genital area was scanned. By warning them in advance, this avoided any anxiety or surprises.
- During the scan, the provider gave detailed and thorough explanations of everything observed, pointing out what they saw to the parents and outlining what this meant in terms of growth and development.
- At the end of the appointment, the provider gave the patients a variety of photos from their scan and a written report of findings. They also verbally summarised these results and explained what to expect next in their NHS appointment programme. Patients were not pressed to return to the clinic for further scans. If they did want further scans, the provider suggested the best weeks, based on their gestation, to provide the most useful information.
- There was a price list on view on the reception desk, as well as displayed on the clinic's website, so patients were fully aware of the costs of procedures.
- The service had received 93 compliments in the year to 5 November 2018.

Are diagnostic imaging services responsive?

Service delivery to meet the needs of people using the service

Good

The service was planned and provided in a way that met the needs of people using the service.

• The clinic was a converted mill and had been designed specifically to meet the provider's brief for high quality, patient friendly premises.

- It was located in a peaceful, rural setting and designed to create a relaxing and comfortable environment for patients. The patients we spoke with were positive about all aspects of the clinic.
- The Beard Mill Clinic website was clear and informative. It included guidance on the different types of services offered. The explanations were detailed and highlighted when it would be best to carry out different types of tests, and what they would show. For example, the website included a section on 'Reasons for having a non-invasive prenatal test (NIPT) at Beard Mill Clinic' and outlined why the provider would perform a scan at the same time at the NIPT blood test, for additional information, and the type of results to expect.
- The clinic also had information booklets about the service available in the waiting room, and displayed the most recent CQC inspection report ratings.
- Prices for different services were shown on the website and on display in the waiting room.

Meeting people's individual needs

The service took account of patients' individual needs and put them at the heart of services.

- Patients booked appointments to suit their specific needs, for example taking into consideration their work commitments or travel constraints.
- The provider waived charges for repeat scans under specific circumstances, for example if a patient returned to confirm viability or a miscarriage.
- Beard Mill Clinic sponsored, a charity that provided support and information to parents throughout antenatal testing, and where there has been a diagnosis of fetal abnormality. The provider offered to see any patients referred to them by the charity without payment.
- The service was accessible to people with mobility constraints. There was parking adjacent to the service, and there was wheelchair access throughout the patient areas. The scanning couch could be raised and lowered to help people who needed to transfer from a wheelchair. The toilet was designed to be wheelchair accessible.

- The provider said their longer appointment times meant they scanned a high number of bariatric patients. This was because larger patients often needed longer appointment times to obtain clear images and to take measurements.
- The service offered patients 3D and 4D scans, depending on the gestation of the baby, and patients were given copies of the photos as well as a full report of the scan.
- The provider organised appointments to allow time between patients. This helped improve patient experience, and gave time for the provider to make additional referrals if necessary.
- There was room for patients to bring more than one relative or friend into the ultrasound scanning room.
- The service had not needed to use a translation service, but the provider knew how to access these services if necessary, through their contract with the NHS. The receptionists would alert the provider if they anticipated any particular needs. One patient commented in their feedback 'Dr Victoria is really professional person, she answered all our questions and her answers were very easy to understand (we are not English). Also, she is very kind and friendly'.
- Patient feedback from January 2019 showed patients found it easy to find the clinic.

Access and flow

People could access the service when they needed it.

- The clinic offered patients appointments from Monday to Friday between 8am and 5pm. It was not at full capacity and the provider could often offer patients a same-day or next-day appointments.
- The provider had a telephone service that meant if she did not answer the phone within a defined number of rings, it transferred to a remote reception service. The trained receptionists had access to a shared diary and could book appointments for patients directly. If the provider was away on the chosen day, and the patient was not able to wait until they returned, the receptionists could suggest they contact an alternative private clinic in the area, that provided a similar service.

- The provider gave patients a full report and images, and arranged further appointments, if patients wished, before they left the clinic. If images indicated a need for a referral to the fetal medicine clinic or other NHS services, the provider also aimed to make these referrals before the patient left the clinic.
- There had been no delayed planned appointments for a non-clinical reason in the last 12 months.
- There were only a few patients that did not arrive for their appointment. The provider explained that she handled this sensitively as sometimes this was because the patient had miscarried.
- Patient feedback from January 2019 showed patients found it easy to book an appointment and comments included, 'I chose the time, Victoria accommodated!' People also said they didn't have to wait.

Learning from complaints and concerns

The service had systems to treat concerns and complaints seriously, investigate them and learn lessons from the results.

- The service had not received any complaints in the past year. The provider was responsible for managing complaints, and had systems to manage and respond to complaints or concerns if raised.
- Patients could read the provider's complaints policy on the clinic website or within the information pack made available in the waiting room.
- As the provider undertook all the scans herself, Dr Victoria Heath recognised when a patient might be dissatisfied with the service and was able to take immediate action to improve their satisfaction. She explained that such actions could be providing further explanations or additional scans, for example if the baby had been in a difficult position to get a clear image when they visited.

Are diagnostic imaging services well-led?



Leadership

The provider had the right skills and abilities to run a service providing high-quality sustainable care

- The provider, Dr Victoria Heath, was a sole practitioner at the service, and took responsibility for all aspects of the service, including governance, clinical management, health and safety and quality. The service had two directors, the provider and the company secretary.
- Dr Victoria Heath provided a high standard of clinical leadership, having trained in obstetrics, gynaecology, neonatology and fetal medicine and undertaken research into screening programmes.
- They also managed the non-clinical side of the business, using contracted support services, for example for receptionist services and to maintain equipment and the environment. Before starting their own business, they e had a role in managing a private antenatal screening clinic in London.

Vision and strategy

The service had a vision for what it wanted to achieve and reviewed this based on patient feedback and local engagements with services.

- The service had been set up over 10 years ago, as a private company, to offer ultrasound screening and advice in pregnancy. Its aims were to supplement, and not replace, the antenatal care provided by the NHS, by offering additional screening tests and scans.
- The provider monitored patient feedback to review the quality of service delivery, and make changes where suggested. For example, in 2018 the provider updated the clinic's website to make it more informative and personalised and to highlight its differentiation from other clinics.

Culture

The provider promoted a positive culture combining high quality services and a relaxing, welcoming environment.

• As the provider was the sole employee, the focus of the culture was on creating a high quality, patient focused service, that was appreciated and recommended by those who used or interacted with it.

- The receptionist handbook emphasised the patient-centred values of the service, and importance of raising any patient concerns or complaints with the provider immediately.
- The provider was familiar with the duty of candour but had not needed to apply it.

Governance

The provider had a systematic approach to improving the quality of service.

- Clinical excellence was the focus of the clinic's approach to delivering high-quality patient care. The provider, Dr Victoria Heath, was responsible for clinical governance at Beard Mill Clinic and she had set up systems for monitoring outcomes for patients, comparing results against those developed by the Fetal Medicine Foundation.
- The provider held clinical governance meetings twice a year and reviewed results of audits, feedback from patients and other stakeholders, any incidents or complaints and any new legislation relating to the clinic.
- The provider monitored the quality of cleaning and had set up schedules for environmental and equipment servicing and maintenance.
- The clinics incident reporting procedure did not include what incidents must be reported to other agencies, such as the CQC.

Managing risks, issues and performance

The service had identified some risks and put in plans to eliminate or reduce them, but had not reviewed new risks.

- The provider did not employ locum staff to cover absence. They tended to take one-week holidays and advise patients of this in advance and monitor emails during periods of absence. When the provider was not available the service referred patients to a local, similar service that had agreed to cover these absences.
- The clinic's health and safety prevention and control policy and procedures included risks relating to

manual handling, minimising risks of slips and reporting incidents under the Reporting Injuries, Diseases and Dangerous Occurrences Regulations (RIDDOR).

- The provider had undertaken risk assessments related to key risks associated with the service, but these had not been updated. For example, the risks associated with the change from employing an on-site receptionist to using a telephone reception company had not been identified with mitigations.
- There were systems to manage known, existing hazards, such as those relating to cleaning products, lifting, the proximity to the river and the internal glass bridge over the river.
- The provider was insured through the Medical Defence Union and they had reviewed and confirmed her indemnity in October 2018.

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

- The clinic had an information security policy which outlined how it received, created, used, shared, stored and destroyed electronic and hard copy data. The provider's data protection policy (November 2018) reflected the General Data Protection Regulations (GDPR). The clinic was also registered with the Information Commissioner's Office.
- The clinic's patient registration forms had been updated with additional information about data management. The provider asked patients to complete and sign a personal data consent form. This included requesting patients to consent to sharing information with their GP and other health professionals if directly relevant.
- All electronic systems were password protected, and the provider filed patient records using a unique identifier to support confidentiality.
- The clinic used a recognised obstetric software system, linked to the scanning equipment, which meant measurements and photographs were automatically collected into reports. The ultrasound

scanner also stored data which the provider routinely downloaded and stored securely on hard discs kept in a secure, locked cabinet within the building. The provider kept hard and electronic copies of all reports.

• The provider gave patients copies of their reports and a selection of photos from the scan.

Engagement

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

- Many patients found out about the clinic through personal recommendations from friends, relatives and from health professionals, including GPs. The provider sought patient feedback directly, via outcome forms included with patient reports, and from annual patient surveys.
- The provider had carried out a 'multi-source' questionnaire in February 2018, based on questionnaires provided by the General Medical Council, to gain feedback on their skills and attributes. This included a self-assessment, feedback from 15 colleagues in the NHS service and 30 patient responses. The organisation coordinating the survey benchmarked results against over 900 doctors working in clinical settings and 900 'colleague' data results.
- Results showed all feedback from patients was at the highest level, very good. The provider scored in the top 25% for questions such as being polite, making you feel at ease, listening to you, assessing you, involving you in decisions. Feedback from colleagues was all good or very good, on topics such as clinical knowledge, diagnoses, clinical decision making, record keeping, keeping up to date, commitment to care and wellbeing of patients and respecting patient confidentiality. When compared against benchmark data the provider was in the highest 25%.
- The questionnaire showed good engagement with other health professionals. Comments included 'I often refer patients to Victoria...she sends very comprehensive notes explaining her can findings and plan', 'Referrals we have received from Victoria Heath have always been well documented and ladies have

been well informed' and 'I frequently recommend Dr Heath to my patients'. A health professional in antenatal screening said Dr Health kept them well informed with updates regarding patients.

• A recent survey of 27 patients, carried out in January 2019, asked relevant questions about the quality of service and patients' experiences of care. The survey also asked patients for comments and overall impressions. The results were consistently positive and indicated a very high level of satisfaction.

Learning, continuous improvement and innovation

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

- The provider maintained a folder evidencing the additional courses they had attended as part of their continuing professional development. The provider also maintained their honorary contract with a London NHS trust to keep up to date with skills.
- They had also introduced presentation folders for the report and photographs, in response to feedback that suggested these would create an attractive keepsake.

Outstanding practice and areas for improvement

Outstanding practice

The provider had a range of approaches to assess their quality of practice. These included reviewing results

against benchmarked data, evaluating patient feedback against fetal measurements and obtaining peer reviews on their own performance. This demonstrated a strong commitment to providing high quality patient care.

Areas for improvement

Action the provider SHOULD take to improve

- The provider should risk assess being the only person on site at Beard Mill Clinic, to protect their safety and that of their patients.
- The provider should risk assess the non-clinical cleaning materials used on the premises, in line with the Control of Substances Hazardous to health (COSHH) regulations.
- The provider should reference details on the types of incidents that must be reported to other agencies, such as the CQC, in the incident reporting policy.