Lanes Medical Practice: Polar Diagnostics LLP

Quality Report

Lanes Clinic
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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	Requires improvement
Are services safe?	Requires improvement
Are services effective?	Not sufficient evidence to rate
Are services caring?	Not sufficient evidence to rate
Are services responsive?	Good
Are services well-led?	Requires improvement

Summary of findings

Letter from the Chief Inspector of Hospitals

Lanes Medical Practice accommodates a women's scan clinic which is operated by Polar Diagnostics LLP under a practising privileges contract. The clinic offers the following scans to self-funding women aged from 18 years, as outpatients' appointments:

Early pregnancy scans

Dating Scans

NIPT (a non-invasive prenatal test)

Gender scans

Growth Scans

Foetal wellbeing scans to include 3D or 4 D images.

Pelvic scans

Fertility related scans for follicle tracking or endometrial thickness

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

The clinic has a CQC registered manager who is a sonographer and another part time sonographer who is also employed at a local NHS trust.

The scanning facility occupies a single room at Lanes Medical Practice and shares their waiting area, the receptionist, kitchen, toilets and some office space.

We inspected the scanning service using our comprehensive inspection methodology. We carried out a short-notice announced inspection on 28 November 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.

This clinic had not previously been inspected or rated using the current methodology.

We rated it as **Requires improvement** overall because:

- The clinic's safeguarding adult procedure did not reflect up to date guidance in relation to safeguarding adults. The provider did not have a policy in place to safeguard children. There was no formal process to manage safety incidents and learn lessons from them.
- There was no process to ensure staff were registered to practice or that they had completed mandatory training, or that the appropriate pre-employment checks were undertaken.
- The clinic had no overarching governance process or system to identify and mitigate risk, or improve quality and performance. There was no vision and values document to ensure staff were clear about the direction of the clinic or personal accountability for the quality of service.

However, we found that:

Summary of findings

- The clinic had enough staff to care for women and keep them safe, and controlled infection risk well. Staff were able to respond quickly if women became unwell, to keep them safe.
- Staff worked well together for the benefit of women and supported them to make decisions about their care. Staff audited practice and maintained their skills and competence to provide quality care. The clinic was available for appointments six days per week.
- Staff respected women's privacy and dignity and took account of their individual needs, helping them to understand their conditions. They provided emotional support to women, families and carers.
- The clinic planned care to meet the needs of local women, took account of women's individual needs, and made it easy for people to give feedback. Women could access the clinic when they needed it and did not have to wait too long for their scans.

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	**Requires improvement** 	The provision of ultrasound scanning services, which is classified under the diagnostic imaging core service, was the only service provided by Polar Diagnostics LLP We rated this clinic as requires improvement because it did not have effective governance systems in place, to manage risks, and monitor quality. The clinic did not have strong pre-employment checks and safeguarding processes were out of date and unreliable.

Summary of findings

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Summary of this inspection

Background to Lanes Medical Practice: Polar Diagnostics LLP

Lanes Medical Practice is in Stoke Poges near Slough in Buckinghamshire. Lanes Medical Practice accommodates a women's scan clinic which is operated by Polar Diagnostics LLP The clinic offers the following scans to self-funding women aged from 18 years, as outpatients' appointments:

Early pregnancy scans from five weeks

Dating Scans

Non-invasive prenatal testing (NIPT)

Gender scans

Growth Scans

Foetal wellbeing scans to include 3D or 4 D images.

Pelvic scans

Fertility related scans for follicle tracking or endometrial thickness

The clinic has had a registered manager in post since December 2012 and has operated from the Lanes Medical Practice since June 2017. Scanning is available Monday to Friday between the hours of 10am and 12pm and 2pm and 5pm. The clinic also operates on Saturday mornings between 10.30am and 12pm. Sonographers complete approximately 80 scans per month.

Our inspection team

The team that inspected the services provided by the clinic comprised a CQC lead inspector and a specialist advisor with expertise in diagnostic imaging. The inspection team was overseen by Catherine Campbell, Head of Hospital Inspection for South East Region.

Information about Lanes Medical Practice: Polar Diagnostics LLP

The clinic has one ultrasound scanning room and is registered to provide the following regulated activities:

- Diagnostic and screening procedures

During the inspection we viewed all the facilities available to the clinic, which were shared with the Lanes Medical Practice; these included the waiting area, kitchen, toilet store room and office space. This location had been inspected by CQC in April 2018.

The focus of our inspection was the scanning room and clinical services provided by Polar Diagnostics.

We spoke with the registered manager and reviewed customer feedback forms. On the day of our inspection there were no scheduled scans taking place, so we were unable to observe any clinical activity.

There were no special reviews or investigations of the clinic undertaken by the CQC during the 12 months before this inspection and the clinic had not previously been inspected.

Activity from October 2018 to July 2019.

The clinic staff did not keep detailed records of the number of scans completed but told us they undertook about 80 scans per month.

Track record on safety for the period October 2018 to July 2019:

- No clinical incidents.
- No serious injuries.

The clinic received one complaint in July 2019.

Services provided at the clinic under service level agreement:

Summary of this inspection

- Maintenance of ultrasound equipment.

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?

Requires improvement

We rated the clinic as **Requires improvement** because:

- We were not assured there were effective systems and processes to support staff in identifying safeguarding concerns.
- Pre-employment checks were not undertaken prior to staff working at the clinic.
- There was no in-house mandatory training for staff, in fire safety, manual handling or health and safety for example.
- The clinic did not complete any clinical risk assessments.
- There was no documented plan for the management of unexpected events such as bad weather or staff sickness.
- There was no incident reporting and management procedure.

However:

- The clinic controlled infection risk and kept premises and equipment clean.
- The clinic had enough staff to provide the right care and treatment.
- Equipment was well maintained and suitable for the procedures performed

Are services effective?

Not sufficient evidence to rate

We do not rate effective for this type of service, we found:

- The clinic did not have a written care pathway for staff to follow when referring women to NHS services when finding an abnormality or health concern.
- Staff did not receive appraisals and managers did not formally review staff competency.
- The clinic did not have a Mental Capacity Act (2005) policy and the registered manager had not received specific training.

However:

- Staff followed National Institute for Health and Care Excellence NICE guidance and Royal College of Obstetricians and Gynaecologists guidelines.
- Staff audited image quality and report writing accuracy

Are services caring?

Not sufficient evidence to rate

We did not rate caring because we were unable to observe any clinical practice or interactions between the staff and patients:

Summary of this inspection

- Service user's views on the service was monitored through feedback questionnaires.
- The clinic provided emotional support for patients receiving bad news.
- Staff provided advice to patients on what to do if they had concerns and made appropriate referrals to other services when necessary.

Are services responsive?

Good

We rated it as **Good** because:

- The clinic offered a range of appointment times and days to meet the needs of the women who used the service.
- The facilities and premises were appropriate for the services that were planned and delivered.
- The scanning room had a large wall-mounted screen which projected the scan images from the ultrasound machine allowing families to see the images produced clearly.
- The clinic was able to accommodate the needs of wheelchair users and extend appointment times for those with other disabilities where necessary.
- Women received information on how to make complaints when they registered with the clinic.

Are services well-led?

Requires improvement

We rated it as **Requires improvement** because:

- There was no governance oversight and systematic procedures to ensure clinical practice was of the highest quality.
- Pre-employment and professional registration checks were not undertaken to ensure sonographers were registered to practise.
- There was no routine formal appraisal of overall staff performance.
- There was no embedded method of capturing and managing risk.
- There was no formal business continuity plan to ensure the running of the business in the event of an emergency.
- There was no routine engagement with staff or women to monitor the service and effect change.

However:

- Staff maintained electronic patient information in accordance with the data protection act

Detailed findings from this inspection

Overview of ratings

Our ratings for this location are:

	Safe	Effective	Caring	Responsive	Well-led	Overall
Diagnostic imaging	Requires improvement	Not rated	Not rated	Good	Requires improvement	Requires improvement
Overall	Requires improvement	Not rated	Not rated	Good	Requires improvement	Requires improvement

Notes

Requires improvement

Diagnostic imaging

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

Are diagnostic imaging services safe?

Requires improvement

We rated it as **requires improvement.**

Mandatory training

The clinic did not provide mandatory training in key skills to all staff and did not make sure everyone completed it.

The clinic did not provide mandatory training or updates for staff. The registered manager was part-owner of the clinic. A part-time sonographer was employed on a zero hours contract. The registered manager told us their colleague completed all mandatory training within their NHS employment.

The 'staff handbook' did not refer to any mandatory training; there was a large section on responsibilities under health and safety legislation and the policies relating to this, but there was no evidence that staff had seen this.

There was no indication that mandatory training was updated on a regular basis.

The registered manager had completed external, online, mandatory training courses in November 2019. This training included infection prevention and control, equality and diversity, complaints management, consent, safeguarding adults' level 1 and chaperoning. They explained that they had previously completed these training sessions in 2017.

There was no in-house training for fire safety, manual handling or health and safety but we saw evidence of equipment training records from July and August 2019.

Following our visit the manager provided training records for the sonographer employed by the clinic. This was completed in their NHS employment and included, for example, dementia awareness, conflict resolution, infection prevention and control, moving and handling, data security, adult basic life support and others. The training was appropriate to the service provided at this clinic, but did not include location specific training such as fire safety and manual handling.

Safeguarding

We found not all staff received the expected level of training required to protect women and their families from abuse and the clinic did not have a clear and up to date process for reporting abuse.

The registered manager, as clinic lead received online safeguarding adults training to level one and did not complete any training in safeguarding of children. When questioned they were unsure of the process or what level of safeguarding they required.

The Intercollegiate document 'Safeguarding Children and Young People: Roles and Competencies for Healthcare Staff' identifies six levels of competence, and gives examples of groups that fall within each of these. Clinical staff who, in their role, have contact (however small) with children, young people and/or parents/carers or adults who may pose a risk to children should be trained to level 2.

There was no record of safeguarding training for the other sonographer and the manager did not know what level of

training they received in their NHS role. Following the inspection the manager requested details of safeguarding training completed by their sonographer colleague. We saw that safeguarding training had been completed at level 2 for children and adults and was valid until March 2021 and October 2021 respectively.

The safeguarding poster on the wall in the clinic was out of date and the manager was unsure if the numbers for the local authority safeguarding team were current. There was a risk that the safeguarding information was out of date and, if followed, relevant actions could be missed.

The clinic provided a copy of a safeguarding policy. This was 'The Buckinghamshire Safeguarding Vulnerable Adults Board Multi-agency policy and procedures valid from April 2012 to April 2013'.

The manager was aware of female genital mutilation and knew it was necessary to refer cases to social services but had never needed to do so.

The registered manager had not requested disclosure and barring service (DBS) checks specific to the clinic. The manager told us that staff had a DBS certificate from their local NHS employment and did not realise that a check specifically for the clinic was required. Following our visit the sonographer applied for and received a DBS certificate applicable to the clinic.

Cleanliness, infection control and hygiene

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

The registered manager was the infection control lead and had completed some online training in infection prevention and control. We saw evidence the other sonographer completed infection prevention and control training as part of their NHS employment.

At the time of our inspection the clinic environment was visibly clean and tidy. The host Lanes Medical Practice employed a cleaner; the clinic was cleaned each evening and a cleaning log completed. The clinic had access to the cleaner during the day, so the sonographers could request extra cleaning if needed.

A deep clean for infection control purposes had never been required but the manager was able to describe how they would arrange for a deep clean, and a specific cleaning pack was available.

The Lanes practice manager audited cleaning weekly and the manager told us any concerns were addressed immediately.

We saw hand washing facilities in the scanning room and hand sanitising gel was available in other areas of the premises. This was in line with epic3: 'National Evidence-Based Guidelines for Preventing Healthcare-Associated Infections in NHS Hospitals in England' (epic3) and Health Technical Memorandum (HTM) 00-09.

All waste was kept in a clinical waste bin until collected which was arranged by Lanes Medical Practice.

There was specific training provided to staff in January 2019 for cleaning the ultrasound probes. The manager demonstrated the process which was in line with 'Infection prevention and Control in Ultrasound – Best Practice Recommendations from the European Society of Radiology Ultrasound Working Group'.

According to current guidelines the batch numbers of the cleaning products used for the probes should be recorded. This was to provide an audit trail in the event of any women contracting an infection which may have started following their attendance at the clinic. The manager acknowledged they were aware of this requirement, but were not compliant at the time of our visit.

Environment and equipment

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

The clinic was located in a single storey building owned and maintained by Lanes Medical Practice, which shared the waiting area with the women and families attending the clinic.

The area was clean, bright and warm with adequate toilet facilities which were accessible to wheelchair users.

The resuscitation equipment was held in the practice office, in a clearly marked drawer. The practice documentation had been reviewed in Feb 2018. The

guidelines were signed in January 2018 with a note saying they were valid for five years from 2015. There was an up to date weekly check of resuscitation equipment with signatures.

The scanning room was located next to the reception just off the waiting area. The room was small but there was appropriate lighting, and enough space to accommodate the woman and family members.

The room was equipped with an ultrasound machine and a printer, an examination couch and some chairs, a wash basin and some storage. The equipment used was appropriate for the ultrasound procedures provided. The clinic had one ultrasound machine and the manufacturer provided the maintenance and servicing.

The ultrasound equipment was new in July 2019 and still under warranty so there was no record of servicing, but we saw that a serving contract was prepared and awaiting agreement.

The image quality was checked as part of a quality assurance process which included audit of the sonographers' practice.

There was sufficient storage for equipment, and we observed unused items such as wipes, and paper stored in a locked storage cupboard. Staff had access to equipment such as gloves, hand gel and ultrasound gel. All ultrasound gels were in date.

The couch in the scanning room was owned by the Lanes Medical Practice and we saw that this was serviced annually. The couch could accommodate a maximum weight of 150 kilograms.

Assessing and responding to patient risk

Staff did not routinely complete risk assessments to minimise risk for service users.

We found no clear guidance in response to an emergency or serious concern such as if a woman became unwell or needed urgent medical attention. However, the manager told us that the healthcare professionals on site were available and able to monitor a woman's blood pressure should she be feeling faint for example, or in the case of more serious emergency they would call 999 for an ambulance. This had not been necessary in the history of the clinic.

There was no evidence the staff in the clinic used the 'Paused and Checked' checklist recommended by the British Medical Ultrasound Society (BMUS) and Society of Radiographers.

Women were asked their date of birth as part of the initial contact with the clinic and if they were under the age of 18 they were not given an appointment. However when a woman was attending for the first six week pregnancy scan the clinic staff relied on what women told them and did not ask for evidence of date of birth on attendance.

The clinic partners included a consultant obstetrician and a GP, both were available on the phone for sonographers to access if they needed medical advice during a scanning procedure.

If foetal abnormalities were seen during non-invasive prenatal testing (NIPT) the registered manager was trained to deliver the bad news to women. If necessary she would refer the patient to her colleague and business partner, who was a consultant obstetrician. NIPT is a method of determining the likelihood of a foetus having certain chromosomal abnormalities. This blood test analyses small fragments of DNA that circulate within a pregnant woman's blood.

The clinic did not have a specific care pathway for referrals to NHS midwifery services following an abnormality found during a pregnancy scan. However, women were advised to attend their local midwifery services and were given a report, which detailed the findings of the scan to take with them.

Sonographers used their clinical expertise to decide if an urgent report was required and if any action needed to be taken. The manager gave examples of actions following a scan, for example evidence of an ectopic pregnancy or signs of a failed pregnancy. In those circumstances the patient would be referred to the emergency department or the early pregnancy unit as appropriate. A gynaecological abnormality would be referred to a consultant or GP. However there was no evidence of 'closing the loop' to ensure clinicians acted on urgent reports or unexpected findings apart from the initial telephone contact with the local NHS Early Pregnancy Unit (EPU), or emergency department.

Diagnostic imaging

We saw an example of identification details stored in the ultrasound equipment. This contained the date, patient name, date of birth, and date of last menstrual period where appropriate.

The manager told us that hospital notes were sometimes available and used for establishing or confirming the correct patient history and to confirm patients were over 18 years old.

Sonographer staffing

The clinic had enough staff with the right qualifications, skills, training and experience to keep women safe from avoidable harm and to provide the right care and treatment. Managers regularly reviewed and adjusted staffing levels.

The scans were undertaken by the registered manager and a part-time sonographer, both were also registered radiographers with the Health and Care Professions Council (HCPC). There were no other support staff employed.

The manager felt the staffing level worked well. There were enough staff available for the number of scans requested, and they had not been in a position where they had required more. The manager monitored demand and arranged staff for the sessions as necessary.

The sonographers were available six days a week. There was no additional demand or pressure on the clinic at the time of the inspection. The manager was confident that if demand was to increase, the clinic had the capacity to increase the number of sessions per week using the existing staff.

The clinic did not use agency or bank staff, in six years there had been no requirement for them.

No lone working was carried out at the clinic, staff employed by Lanes Medical Practice were on site during the week or a second sonographer was present on Saturday mornings.

Medical staffing

Two doctors were owner partners in the scanning clinic, a GP and a consultant obstetrician, neither were based at the location, both were employed in local NHS services. They supported the clinic when required, for example the obstetrician undertook audit of the sonographers' scans and reports.

Records

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

The clinic obtained health information for women prior to their scan with the pre-assessment questionnaire. For example, number of pregnancies, health conditions and reasons for scan.

Imaging reports completed by the sonographers were comprehensive and complete. Each report contained the unique number of the scanning machine used along with the date the image was taken. A clinical history and reason for the scan was included along with a report of the scan. Each report also included the name of the sonographer.

The sonographers gave women a copy of their report to take to their GP or midwife.

Medicines

The clinic did not store or administer medicines.

Incidents

There was no formal incident reporting system.

During our inspection the manager shared an incident relating to a discrepancy between a report from a scan completed in the clinic and a scan completed a few days later in an NHS setting. The incident had been discussed within the team and learning had been implemented with a change of practice around the wording and emphasis of such reports.

It was clear the team learned from incidents but there was no formal recording or documentation to enable wider shared learning and transparency.

There was no documentation or policy relating to the duty of candour. Staff were aware of the term duty of candour, they understood the need to be open and honest with women if incidents occurred. Duty of candour is a regulatory duty that relates to openness and

transparency and requires providers of health and social care services to notify women (or other relevant persons) of certain 'notifiable safety incidents' and provide reasonable support to that person.

The clinic did not have any policies relating to incident management and they had not declared any serious incidents.

Are diagnostic imaging services effective?

Not sufficient evidence to rate

We do not rate effective for this type of service.

Evidence-based care and treatment

The clinic provided care and treatment based on national guidance and best practice. Managers checked to make sure staff followed guidance.

There were no policies or procedures written specifically for the clinic, however we saw evidence the sonographers followed The National Institute for Health and Care Excellence NICE guidance (NICE). For example, Ectopic pregnancy and miscarriage: diagnosis and initial management NICE guideline [NG126] April 2019.

Sonographers followed guidelines from the Royal College of Obstetricians and Gynaecologists (RCOG), for example Placenta Praevia and Placenta Accreta: Diagnosis and Management Green-top Guideline No. 27a; and the North West London referral guidelines. These guidelines were introduced by a collaboration of clinical commissioning groups in London on a range of topics for use in primary care including documents relating to gynaecological and fertility issues.

The sonographers audited each other's images for quality, demonstrating anatomy, and accurate interpretation of images. The consultant obstetrician and business co-owner also audited report writing by retrospectively reviewing 5% of the sonographers' scans. We saw the reports this clinician produced, which were completed using a series of questions with a tick box response. There was no evidence that sonographer conclusions matched their own or that discrepancies were discussed other than an occasional comment for the sonographer. We were not assured the audits were complete; there was no evidence of a monthly report detailing the discrepancy profile of each sonographer (as stated in the sonographer hand book)

The manager demonstrated use of the software tools inherent to the scanning equipment which were used to record and store the images and facilitate audit. We saw that image and report audits were undertaken every few months.

We saw equipment records which showed technical details of the images, and the sonographer interpretation and report. These were of good quality, comprehensive and well written.

Nutrition and hydration

There were no hot drinks or food provided for women who attended for ultrasound scans. Staff were able to provide drinking water to women if they requested this or if they felt unwell during the scan.

Women were advised to eat and drink as normal before the scan. If the woman was less than 20 weeks pregnant, they were advised to arrive with a full bladder to help ensure the best view of their baby.

Pain Relief

Staff did not formally assess women's pain levels as the procedure was usually pain free. The manager told us women were asked by staff if they were comfortable during the scanning process.

Patient Outcomes

Information about the outcomes of patient care and treatment was not routinely collected or monitored.

The manager told us that monitoring patient outcomes for the clinic was difficult, but they did use patient feedback to monitor patient outcomes. For example, if their pregnancy had been successful, or if they had not been happy with the support or treatment outcomes.

When staff saw abnormalities on a scan, they made referrals as appropriate to other services, and were trained to deliver bad news when necessary. The clinic did not have any means of following up whether women acted on any advice given.

Competent staff

Requires improvement

Diagnostic imaging

The clinic did not have a formal process to ensure staff maintained competency for their roles.

There were no formal competency records for the sonographers at the time of the inspection. The manager explained that as they were such a small team, they discussed practice informally 'all the time'. Sonographers and partners were able to share knowledge gained from their roles in the NHS and from their membership of The British Medical Ultrasound Society (BMUS).

We saw recent training records for the manager which included; ultrasound July 2018, early pregnancy July 2016, foetal abnormality July 2019, later scans July 2019 (pregnancy). The manager did not routinely check for any formal training undertaken by their colleagues. However, they told us that the consultant obstetrician and the sonographers often shared learning. For example the sonographer who was employed in the NHS took the lead on updating the team regarding the guidelines for disinfecting and cleaning the ultrasound probes.

We saw equipment specific training records; the clinic had acquired a new ultrasound machine in July 2019 and both sonographers had received the applications training from the manufacturer.

The staff handbook included a comprehensive competency matrix, which had been developed by the manager for potential new recruits but at the time of our inspection it had not been utilised and the current team of staff had not received appraisals. This meant that opportunities for development were not formally discussed or recorded.

Sonographers peer reviewed each other's practice through audit, and performance was discussed with the sonographer completing the procedures, and the sonographer completing the peer review. However, there were no actions clearly identified to improve performance.

Multidisciplinary working

All staff worked together as a team to benefit service users. They supported each other to provide good care.

The manager explained how the clinic worked, which most days involved one sonographer on site. There was little multidisciplinary work evident, though when medical advice was required the sonographer could access the consultant obstetrician on the phone, and women could be referred for further consultation.

There was no routine contact between the clinic and women's GPs or maternity services. However, as part of the woman's care, the sonographer would complete a referral form for women to take to NHS services following a detection of a possible abnormality.

Seven-day services

The clinic had appointments available each morning and afternoon Monday to Friday and a session on Saturday mornings. The registered manager advised the number of appointments met the demand for the service.

Consent and Mental Capacity Act

Staff were aware of the importance for gaining consent from women before conducting any procedures.

If there was any doubt about a woman's understanding of the procedure or their ability to sign a written consent form, the sonographers would not complete the scan. The clinic did not scan women who were unable to give informed consent.

We saw the registration form completed by women at the time of appointment giving written consent to carry out the scan. The manager explained that a full explanation of the procedure was given by the sonographer and a written report printed for the women to take away with them.

The clinic did not have a Mental Capacity Act (MCA) 2005 policy. There was no reference to safeguarding or MCA in the staff handbook. MCA training was not undertaken by staff as part of their mandatory training.

Are diagnostic imaging services caring?

Not sufficient evidence to rate

We were not able to inspect this domain as at the time of our inspection we did not observe care being delivered.

Compassionate care

Requires improvement

Diagnostic imaging

We were unable to observe any interactions between staff and women.

The clinic manager provided contact details for women who had agreed for us to contact them, however we did not receive any response from the six women we approached.

The clinic offered all women an opportunity to provide feedback on the service they received. We saw numerous completed questionnaires, almost all described the clinic as five star.

We saw a notice for women offering a chaperone if requested, the manager explained there was always a member of staff from Lanes medical Practice team available to support the sonographers.

Emotional support

The manager explained that if a scan identified an abnormality, staff explained the results from the scan, to the woman and those accompanying them, in a supportive way. The sonographer gave the woman and her family time, and explained the next steps to the women. A report was provided and staff advised the woman to attend their local NHS midwifery services.

The manager was trained to deliver bad news and there was access to a private room to do so. If required, women were referred to the clinic's consultant obstetrician when necessary.

Understanding and involvement of women and those close to them

At the end of all procedures, women were given advice on what to do if they had concerns around their health and wellbeing.

Women, attending for pregnancy scans, were advised to contact their midwives if they had concerns following their appointment. For women who attended for non-pregnancy related scans, staff advised them to contact their general practitioner if they had concerns following the scan.

No aftercare leaflets were available, the sonographer was able to describe how they made sure women knew how to access the early pregnancy unit (EPU), or the local emergency department.

If women were referred on to their local early pregnancy unit (EPU), the sonographer contacted the unit to advise that a patient was being referred and the reasons for the referral.

At the end of the scan, staff discussed any information they found, and provided the woman with a copy of the scan report. This provided women and their relatives with another opportunity to ask any questions about the procedure they had just experienced before leaving the clinic.

Are diagnostic imaging services responsive?

Good

We rated it as **good.**

Service delivery to meet the needs of local people

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

The clinic was not established to provide emergency services. Access to the clinic was on a planned basis with appointments booked in advance. People wishing to book an appointment for a scan were able to do so by contacting the clinic by phone or in person.

The clinic offered a range of appointment times and days to meet the needs of the women who attended. The manager told us they made sure women were able to book appointments to fit in with their work and family commitments. They explained, there was a flexible appointment system and were often able to scan women on the day of their request, reducing anxiety and giving timely reassurance when women needed it the most.

Scans associated with fertility treatment were required to be performed according to the women's treatment cycle; the clinic was able to accommodate this requirement and provide a report before the fertility clinic prescribed further medication or modified the dose. This service was available to women who were receiving fertility treatment abroad. It meant that scans could be completed within the necessary timeframe without the need for women to incur the expense of extra travel abroad just for the purposes of a scan.

Diagnostic imaging

The scanning room had a large wall-mounted screen which projected the scan images from the ultrasound machine. This screen enabled women and their families to view their baby scan more easily and from anywhere in the room. This was in line with recommendations (Royal College of Radiologists, Standards for the provision of an ultrasound service December 2014).

Meeting people's individual needs

The clinic staff were inclusive and took account of women's individual needs and preferences. Staff made reasonable adjustments to help women access the clinic.

The staff gave women enough time during scan appointments, and the feedback we saw from the women indicated that they did not feel rushed during their scan.

The clinic was wheelchair accessible and there was access to a private room where women and family members could go following difficult or distressing news.

The couch used for scanning allowed for women weighing up to 150 kilograms.

The door to the scanning room was lockable from the inside which ensured privacy and dignity for the women during scans; this was particularly important for women who were undergoing internal scans.

Women were not provided with written information in accessible formats before appointments. There were no appointment letters sent to women, information was given verbally at the time of making the appointment.

When women made the initial contact with the clinic, this was made by telephone and if there were language difficulties staff could access a 'pay as you go' translation service available through the Lanes Medical Practice.

The manager was multi lingual and could speak and understand Hindi, Urdu, and Punjabi, and the clinic could source information material in Polish upon prior request. The manager said they would sometimes rely on family members who accompanied women who's first language was not English. This was not in accordance with best practice.

The clinic had never received an appointment request from women with dementia or a learning disability, but the manager was clear that appointment times were flexible and could be extended to ensure there was sufficient time to accommodate a woman who may need extra time for explanations.

Access and flow

People could access the clinic when they needed it and received the right care promptly.

The clinic did not have a waiting list, most appointments were arranged within a day or two of the patient contacting the clinic, or within a timeframe which suited them and their clinical need. However, there was also the opportunity to book appointments for the same day.

If women needed to change their appointments they would contact the clinic and the provider would offer an alternative appointment or a refund of the deposit depending on the reason for cancellation or length of notice given.

The clinic had re-arranged appointments just once during the previous year due to equipment breakdown. The clinic did not collect data on women who did not attend appointments.

Women who did not attend for their appointment were those who wanted their first six week pregnancy scan, and after booking possibly found a cheaper alternative or miscarried the baby. The clinic did not ask for a deposit therefore were unable to make further contact with those women.

Learning from complaints and concerns

It was easy for people to give feedback and raise concerns about the care they received. The clinic treated concerns and complaints seriously, investigated them and shared lessons learned with all staff.

The initial contact form for registration with the clinic provided the women with information on what they should do if they wanted to make a complaint.

The clinic had received only one complaint during the year prior to our inspection. The manager described the concern and the actions taken to ensure the complainant understood the reasons for the discrepancy in clinical reports she had received. The complaint was resolved with full involvement of the patient.

Requires improvement

Diagnostic imaging

The registered manager collated comments received via the website and social media comments. All the comments we saw were positive about the clinic.

The clinic referred to a complaints procedure in the staff handbook but there was no requirement to formally acknowledge a complaint and no indication of timescales for response to complaints.

Are diagnostic imaging services well-led?

Requires improvement

We rated it as **requires improvement.**

Leadership

Leaders had the skills and qualifications to run the clinic but employment records were limited and formal processes for quality improvement had not been established.

The clinic was led by the registered manager who was one of the original founders of the service. The business was co-owned and supported by a consultant obstetrician and a local GP. The consultant obstetrician provided clinical support to the sonographers.

The manager was visible and available to staff and women attending for scans. They were knowledgeable about the clinical service and provided advice to women about their scans and to those who were referred to other providers.

The registered manager told us they kept up to date with the British Medical Ultrasound Society (BMUS) and we saw evidence of links on the service's website.

There was no recognition by the manager that formal policies and processes were required, to ensure the quality of the service could be monitored effectively. For example, there were no local policies applicable to the clinic function.

There was no formal system for monitoring sonographer competency or providing formal performance feedback to staff as there was no appraisal process. This posed a risk that care provided could be of a variable standard, although the registered manager advised that sonographers reviewed each other's scans for quality.

The registered manager was subject to a pre-employment check through the Disclosure and Barring Service (DBS) and we saw this had been done, however there was no record the manager had checked the other sonographer was registered with the DBS prior to employment. This was rectified following our visit, and evidence provided to us.

Vision and strategy

The clinic manager had a vision for what they wanted to achieve and an idea of how they might ensure the service was sustainable but this was not formally documented.

The manager was happy with the current level of business but they were considering options to grow the business in collaboration with a national provider. They were aware that competition was growing locally and wanted to remain a viable service. The plans for sustainability were not recorded and succession plans for service continuation had not been formally discussed with relevant staff.

Culture

We were unable to reflect in detail on the culture of the service at this inspection due to the lack of clinical activity on the day.

The inspection visit took place when there were no scans scheduled and only the manager on site. This did not allow us to assess the culture of the service in any detail.

Our findings from discussions with the manager were of a professional service that focussed on the needs of the women attending. The experience of the women was good as evidenced by the feedback comments.

Staff relationships were informal and friendly, and both sonographers were able to discuss ideas, and share views. The partners provided clinical support when required and met regularly with the manager to discus business issues, these meetings were not structured but conducted in an informal social environment.

There appeared to be a 'no blame' culture within the service. The registered manager explained they would discuss with staff if a complaint had been made and would contact the complainant as soon as possible to discuss concerns raised. The manager gave an example of this.

Requires improvement

Diagnostic imaging

Governance

The clinic did not systematically improve service quality and there was a lack of overarching governance processes.

Links to local safeguarding teams and the safeguarding policy issued by the local authority were out of date, and the manager was not sure if the local service was configured in the same way or still existed at the same office. We were not assured staff could make referrals to the local safeguarding team if necessary.

There were no personnel files and no routine method of checking when staff training required renewal or when a disclosure and barring service (DBS) check was required. There was no routine formal appraisal of staff performance. The manager could not be assured that staff remained competent for their role.

There was no systematic governance structure which focussed on clinical issues, for developing and maintaining policies and procedures, or quality improvements to the service provision.

The registered manager worked closely with the other sonographer and any issues, concerns, and clinical advancements were shared between them on an informal basis. The clinic partners met off site periodically for business discussions only.

The clinic had clear infection prevention and control procedures which followed national guidelines and replicated the procedures followed in the local NHS trust.

Managing risks, issues and performance

The clinic did not have systems to identify risks, or plan to eliminate or reduce them.

We saw a documented risk assessment for the practice premises, but there were no risk assessments to identify any clinical risks or demonstrate how the clinic would mitigate any risks identified.

There was no formal business continuity plan to ensure the running of the business and the action staff would take in the event of a major incident. For example, a power cut, severe weather or staff sickness.

The staff did complete some audits, for example image scan quality but this was limited and would not provide wider assurance of quality of its service or inform improvements on any areas of weakness.

The clinic did have indemnity insurance which covered the service and all staff working there.

Managing information

The clinic collected reliable data and analysed it. Staff could find the data they needed, in easily accessible formats, to understand performance, but staff training compliance was not monitored.

Staff used the software built into the scanning equipment for audit purposes. This allowed them to analyse the integrity of their own interpretation and reporting of scans, as well as the quality of the images produced by the machine.

In common with other similar small independent services the clinic did not use the Image Exchange Portal (IEP) or transfer data. The IEP is a web-based application that allows healthcare professionals to securely transfer patient images from one hospital to another. The system has been deployed in increasing numbers of NHS and private hospitals since January 2010. Images and reports were given directly to women following their scans which mitigated any concerns that sensitive data could fall into the wrong hands.

Records of scans were stored on a backup hard drive which was stored in a locked cupboard. The manager was aware that the clinical images needed to be kept for 25 years. Paper registration forms were stored securely in a locked drawer and destroyed every three years.

The staff hand book directed staff to an online training website for information governance, however there were no records that staff had accessed the training modules identified. There was no system or process for monitoring staff compliance.

Engagement

The clinic engaged well with women. Engagement with staff was evident on an informal basis only.

Requires improvement

Diagnostic imaging

The clinic had feedback questionnaires for service user feedback which women and their families were asked to complete. We saw that the clinic received several completed questionnaires each month.

Staff meetings were not held regularly, they lacked structure and were not formally minuted. There was no set timeframe between meetings. We saw some meeting notes from meetings held in November 2017, July 2018, April and October in 2019. There was no rolling agenda for the meetings and did not appear to show discussion on incidents or complaints for shared learning. However we were aware this was done informally between the manager and the other sonographer on a regular basis.

Learning, continuous improvement and innovation

The service was committed to improving services by listening to feedback and sharing learning

A new ultrasound scanning machine was purchased in the last 12 months to improve the quality of images that were produced.

The manager described how the small team worked together to share ideas and to learn from events that went well or wrong.

The clinic used customer feedback to improve the service. The registered manager reviewed complaints and comments and we saw evidence of how change was made following a complaint.

The clinic benefitted from sonographer training completed within their other employment, but we did not see evidence of continued development taking place within the service.

Outstanding practice and areas for improvement

Areas for improvement

Action the provider MUST take to improve

- Staff must complete safeguarding children training at level 2 minimum and ensure a safeguarding policy is written that reflects the local authority provision for the protection of children.
- The clinic must develop overarching governance processes which provide assurance that practice is monitored for quality, risks are identified and managed with mitigation actions, and service improvement opportunities are identified.

Action the provider SHOULD take to improve

- The clinic should develop a mandatory training programme within the service and monitor staff compliance with completion of the programme. The manager should record that it has been completed by staff on an annual basis.
- The clinic should review the practice of relying on accompanying members of the family to interpret women's needs when English or another language understood by the staff and the woman is not possible.
- The clinic should develop a formal incident management procedure which includes reference to the Duty of Candour and ensure staff know how to record incidents. Staff should follow the procedure and share learning from mistakes.
- The clinic should review staff appraisal processes to formally discuss personal and service development opportunities.
- The clinic should consider writing a formal complaints procedure which includes timescales for acknowledgement of, and response to complaints received.
- The clinic should consider arranging a regular meeting for all clinical staff involved with the service to discuss all aspects of the clinical service.

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 13 HSCA (RA) Regulations 2014 Safeguarding service users from abuse and improper treatment (2) Systems and processes must be established and operated effectively to prevent abuse of service users. (3) Systems and processes must be established and operated effectively to investigate, immediately upon becoming aware of, any allegation or evidence of such abuse

Regulated activity	Regulation
Diagnostic and screening procedures	Regulation 17 HSCA (RA) Regulations 2014 Good governance (1) Systems or processes must be established and operated effectively to ensure compliance with the requirements in this part. (2) Without limiting paragraph (1), such systems or processes must enable the registered person, in particular, to— (a) assess, monitor and improve the quality and safety of the services provided in the carrying on of the regulated activity (including the quality of the experience of service users in receiving those services)