

The Oaks Clinic

Quality Report

3 Forest Road
Loughton
Essex
IG10 1DR
Tel: 020 8502 1002
Website: www.theoaksclinic.co.uk

Date of inspection visit: 11 March 2020
Date of publication: 04/06/2020

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?

Are services caring?

Good



Are services responsive?

Good



Are services well-led?

Inadequate



Overall summary

The Oaks Clinic is operated by Mediscan Healthcare Ltd. The service had two clinic rooms, though one was rented out, a waiting room and a toilet.

The service provides antenatal ultrasound scans, antenatal midwifery care, and gynaecology services. These were inspected under the diagnostic imaging core service, as the antenatal scans were the main activity the service provided.

We inspected this service using our comprehensive inspection methodology. We carried out a short notice announced inspection on 11 March 2020. We gave the provider short notice (24 hours) to ensure that the clinic was open for our inspection.

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

Summary of findings

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.

Services we rate

We rated it as **Requires improvement** overall.

We found the following issues that the service provider needs to improve:

- Staff did not always use equipment and control measures to protect women, themselves and others from infection.
- The clinic did not store medicines securely at the time of our inspection. Following the inspection, storage of medicines was improved
- The service did not always provide care and treatment based on national guidance and best practice. Moreover, local guidance was not robust or embedded.
- Staff did not monitor the effectiveness of care and treatment.
- Leaders did not operate effective governance processes.
- Leaders and teams did not use systems to manage performance effectively. They did not always identify and escalate relevant risks and issues or identified actions to reduce their impact.

However, we also found the following areas of good practice:

- The equipment and premises were visibly clean.
- Staff completed and updated risk assessments for each patient and removed or minimised risks. Despite a lack of formal processes, staff were able to identify and act upon women at risk of deterioration.
- 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 registered manager and clinic manager worked together as a team to benefit women. They supported each other to provide good care.
- Staff treated women with compassion and kindness, respected their privacy and dignity, and took account of their individual needs.
- The service planned and provided care in a way that met the needs of local people and the communities served. It also worked with others in the wider system and local organisations to plan care.
- People could access the service when they needed it and received the right care promptly.

Following this inspection, we told the provider that it must take some actions to comply with the regulations and that it should make other improvements, even though a regulation had not been breached, to help the service improve. We also issued the provider with three requirement notices that affected The Oaks Clinic. Details are at the end of the report.

Heidi Smoult

Deputy Chief Inspector of Hospitals (Central)

Summary of findings

Contents

Summary of this inspection

	Page
Background to The Oaks Clinic	5
Our inspection team	5
Information about The Oaks Clinic	5
The five questions we ask about services and what we found	7

Detailed findings from this inspection

Overview of ratings	10
Outstanding practice	22
Areas for improvement	22
Action we have told the provider to take	23

Requires improvement 

Location name here

Services we looked at

Diagnostic imaging

Summary of this inspection

Background to The Oaks Clinic

The Oaks Clinic is operated by Mediscan Healthcare Ltd. The service opened in 2011. It is a private clinic in Loughton, Essex. The service primarily serves the communities of the Essex and Greater London. It also accepts patient referrals from outside this area. All care and treatment is privately funded.

It provides the following services:

- Early pregnancy viability scans
- First trimester screening for Down Syndrome
- Reassurance scans in second trimester
- Gender assessment scans
- Anomaly scans
- Fetal well being scans
- Growth scans
- Uterine artery Doppler scans
- Cervical assessment scans
- Antenatal midwifery care
- Postnatal six week check up
- Antenatal investigations including amniocentesis and chorionic villus sampling
- Cervical smear tests
- Inserting intrauterine contraceptive devices

The clinic has had a registered manager in post since 2011.

Our inspection team

The team that inspected the service comprised a CQC lead inspector and one other CQC inspector. The inspection team was overseen by Mark Heath, Head of Hospital Inspection.

Information about The Oaks Clinic

The clinic is registered for the following regulated activities:

- Diagnostic and screening procedures
- Family planning
- Maternity and midwifery services
- Treatment of disease, disorder or injury

During the inspection, we spoke with the two members of staff; the registered manager and office manager. We spoke with two women. During our inspection, 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. The service has been inspected one time, in 2013, which found that the service was meeting all standards of quality and safety it was inspected against.

In the reporting period March 2019 to February 2020 there was approximately 2000 episodes of care recorded at the clinic. This is an estimate based on the approximation given to us on inspection of 40 to 50 episodes of care a week.

Track record on safety

- Zero Never events
- Zero clinical incidents
- Zero complaints

Summary of this inspection

Services provided at the clinic under service level agreement:

- Clinical waste removal
- Pathology and histology
- Computer database
- Air conditioning maintenance
- Fire extinguisher maintenance

Summary of this inspection

The five questions we ask about services and what we found

We always ask the following five questions of services.

Are services safe?

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

- The service did not always provide mandatory training in key skills to staff and did not make sure everyone completed it. However, we noted that the team was small, with only two members of staff.
- Staff did not always use equipment and control measures to protect women, themselves and others from infection.
- The clinic did not store medicines securely. Following our inspection, suitable storage was put in place.
- There was no formal process to investigate incidents and share lessons learned, although we did see some change to practice as a result of an incident.

However, we also found the following areas of good practice:

- Staff understood how to protect women from abuse however, they did not always have training on how to recognise and report abuse.
- The equipment and premises were visibly clean.
- The design and use of facilities, premises and equipment kept people safe. Staff managed clinical waste well.
- Staff completed and updated risk assessments for each woman and removed or minimised risks. Despite a lack of formal processes, staff were able to identify and act upon women at risk of deterioration.
- The service had enough staff with the right qualifications, skills and experience to keep women safe from avoidable harm and to provide the right care and treatment.
- 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 service used systems and processes to safely prescribe, administer and record medicines.
- Staff recognised incidents and had a form to report them appropriately.

Requires improvement



Are services effective?

We rated it as **Not rated** because:

- The service did not always provide care and treatment based on national guidance and best practice. Moreover, local guidance was not robust or embedded.
- Staff did not monitor the effectiveness of care and treatment.

Summary of this inspection

- The service did not always make sure staff were competent for their roles. Managers did not always appraise staff's work performance.
- Staff did not always support women to make informed decisions about their care and treatment.

However, we also found the following areas of good practice:

- Staff gave women enough food and drink to meet their needs.
- Staff assessed and monitored women regularly to see if they were in pain, and gave pain relief in a timely way.
- The registered manager and clinic manager worked together as a team to benefit women. They supported each other to provide good care.
- Staff gave women some practical support and advice to lead healthier lives.

Are services caring?

We rated it as **Good** because:

- Staff treated women with compassion and kindness, respected their privacy and dignity, and took account of their individual needs.
- Staff provided emotional support to women and families to minimise their distress.
- Staff supported and involved women and families to understand their condition and make decisions about their care and treatment.

Good



Are services responsive?

We rated it as **Good** because:

- The service planned and provided care in a way that met the needs of local people and the communities served. It also worked with others in the wider system and local organisations to plan care.
- People could access the service when they needed it and received the right care promptly.
- It was easy for people to give feedback and raise concerns about care received. The service treated concerns and complaints seriously, investigated them and shared lessons learned with all staff.
- The service was inclusive and took account of women's individual needs and preferences.

Good



Are services well-led?

We rated it as **Inadequate** because:

Inadequate



Summary of this inspection

- Leaders had the skills and abilities to run the clinical aspects of the service but did not have an awareness of the governance aspects of managing the clinic. They did not always understand and manage the priorities and issues the service faced.
- The service did not have a vision for what it wanted to achieve or a strategy to turn it into action.
- Leaders did not operate effective governance processes.
- Leaders and teams did not use systems to manage performance effectively. They did not always identify and escalate relevant risks and issues or identified actions to reduce their impact.
- The service collected reliable data but did not analyse it to understand performance and make improvements. However, the information systems were integrated and secure. Leaders and staff did not always engage with women to plan and manage services.
- Staff were not always committed to continually learning and improving services. They did not have a good understanding of quality improvement methods and the skills to use them.





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	N/A	Good	Good	Inadequate	Requires improvement
Overall	Requires improvement	N/A	Good	Good	Inadequate	Requires improvement

Diagnostic imaging

Safe	Requires improvement 
Effective	
Caring	Good 
Responsive	Good 
Well-led	Inadequate 

Are diagnostic imaging services safe?

Requires improvement 

We rated safe as **requires improvement**.

Mandatory training

The service did not always provide mandatory training in key skills to staff and did not make sure everyone completed it. However, we noted that the team was small, with only two members of staff.

The registered manager had all the required mandatory training necessary for their role which was obtained through their substantive NHS employment. This was sufficient for the role they undertook at the clinic. However, the clinic manager did not complete any mandatory training. There was no policy which outlined what mandatory training the clinic manager should have completed. We raised this as a concern and were told the clinic would source online mandatory training for them. We were later provided with evidence that the office manager had completed safeguarding adults level 1, manual handling and portable appliance testing.

Following the inspection we saw that the service's clinical governance policy was changed to include the requirement for all staff to undertake basic life support, manual handling, adult and child safeguarding, fire safety and Mental Capacity Act training.

Safeguarding

Staff understood how to protect women from abuse, however, they did not always have training on how to recognise and report abuse.

The registered manager had safeguarding adults and children level 3 training from their NHS substantive post. The clinic manager completed safeguarding adults level 1 training, following us raising concerns at the inspection. However, both the registered manager and office manager were aware of their safeguarding responsibilities and were able to give examples of the types of concerns they would escalate. Both staff members knew how to escalate concerns to the local council if necessary.

A children's safeguarding policy was in place; however, this was not dated. Following our inspection the manager updated the policy to include details of authorship, version number, date written and date of review.

The registered manager told us they did not accept women under the age of 18, however, no proof of age was required for women who looked like they may be under the age of 18. We also saw that the age requirement was not recorded in any policy or document. As such, we were not assured that women under the age of 18 would not be able to access the service.

There was no adults safeguarding policy at the time of our inspection. We raised this as a concern and the clinic wrote a policy and sent us a copy. This cited appropriate legislation and provided information on how to make a safeguarding referral.

There was no formal arrangement in place for women to have a chaperone. We were told that most women were accompanied by relatives, but if a woman did require a chaperone there were no arrangements in place for a suitably qualified and trained independent chaperone. This information was not given to women at the booking stage. Following the inspection, we were told that if the clinic became aware of the need for a chaperone, they

Diagnostic imaging

would arrange one. We were told that if the need for a chaperone only became apparent at the appointment, that the examination would be delayed in order to obtain a chaperone or patients would sign a release form.

The registered manager was aware of female genital mutilation (FGM) and child sexual exploitation (CSE). They had received training in both areas through their NHS employment. We were told these were not areas of concern at the clinic due to the demographic of their clientele.

Safety was promoted in recruitment practice, with all staff having valid Disclosure and Barring Service (DBS) checks.

All women were protected against discrimination. Women were not treated differently depending on their protected characteristics under the Equality Act.

Cleanliness, infection control and hygiene

The service did not always control infection risk well. Staff did not always use equipment and control measures to protect women, themselves and others from infection. The equipment and premises were visibly clean.

All areas of the clinic were visibly clean and tidy. An external company was contracted to attend the clinic once per week for cleaning. This process was not recorded and there were no cleaning checklists. We raised this as a concern and were told that a cleaning checklist had been created, however, we were not provided evidence of this.

We observed the registered manager conducting abdominal ultrasounds. We observed them clean the ultrasound probe between women with an antibacterial wipe. However, the registered manager did not wash their hands or use hand sanitising gel between women. We raised this as a concern and were told they only washed their hands between women if they were conducting transvaginal ultrasounds. There were no hand hygiene audits completed at the clinic.

We were told a process was in place for cleaning transvaginal ultrasound probes at the end of clinic, and we saw appropriate cleaning materials available, however, this was not documented. As such, there was no evidence this occurred.

We saw a cleaning cupboard was located in the patient toilet. This was a locked cupboard that contained cleaning materials including bleach. We saw the key was kept in an unlocked drawer in the toilet. We raised this as a concern, especially as we were told women often brought children with them to scans. The office manager removed the key and put it in their desk.

The clinic used disposable sheets for the examination couch, disposable speculums for smear tests and disposable tourniquets when taking blood. This meant they were disposed of after use and did not require cleaning.

Environment and equipment

The design and use of facilities, premises and equipment kept people safe. Staff managed clinical waste well. However, there was insufficient evidence that all equipment was maintained.

The clinic was well designed, with a waiting area/reception, an examination room and a toilet. A second examination room was located in the clinic and was rented out to an osteopath. Osteopathy is not in CQC's scope of regulation, so this room was not inspected.

The ultrasound scanning machine at the clinic was newly purchased in December 2019 and was under warranty. All equipment was in visibly good condition but there was no evidence that regular visual inspections were undertaken, in accordance with Health and Safety Executive (HSE) and Medicines and Healthcare products Regulatory Agency (MHRA) guidance.

The clinic had a proforma for a control of substances hazardous to health (COSHH) assessment, within their policy. However, there was no completed form to show that an assessment had been undertaken. Following the inspection, we were provided with evidence that the clinic had updated their COSHH policy and risk assessment.

The clinic had a contract with a clinical waste disposal firm which came to collect clinical waste as and when needed. We saw a locked clinical waste bin at the clinic and saw sharps containers which were labelled and dated correctly. A process was in place for managing clinical specimens, for example, blood samples. Specimens were stored securely at the clinic and sent by courier to a local pathology laboratory for testing.

Diagnostic imaging

Fire extinguishers were situated by the front door. We checked them and saw that they were in date.

Assessing and responding to patient risk

Staff completed and updated risk assessments for each woman and removed or minimised risks.

Despite a lack of formal processes, staff were able to identify and act upon women at risk of deterioration.

The registered manager completed templated risk assessments for pregnant women, which were based on national tools. This included assessments such as blood pressure and carbon monoxide monitoring. Risk assessments were also conducted for women having contraceptive devices fitted. These included a scan prior to insertion, and a scan following insertion to ensure it was placed correctly. A follow up appointment was also scheduled for six weeks later.

The registered manager had basic life support training. This meant that the registered manager was able to respond if a woman required resuscitation.

A process was in place for checking a woman's identification prior to scanning. This included checking the patient's name and date of birth.

There was no formal policy in place explaining what staff should do in the case of a woman collapsing or suffering an allergic reaction. We saw that adrenaline was available, as was a manual resuscitator. The registered manager had been trained to use these in their NHS employment. We were told that in the event of a woman collapsing the registered manager would use the resuscitation pack as required while the office manager would dial 999 for an ambulance. Following the inspection, the provider created a policy on patient collapse.

A policy was in place which explained that in the event of a suspected ectopic pregnancy, or unexpected findings, the registered manager would refer the patient to their local NHS hospital to be reviewed.

A pathway was in place for the management of cervical smears. We saw that if a smear test came back with an abnormal result the registered manager would write to the patient's GP informing them, so that they could arrange further investigations.

Staffing

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

The clinic was run by the registered manager, who was an obstetrician and gynaecologist, and an office manager. The registered manager worked substantively in the NHS as a consultant. The office manager was clinically trained as an operating department practitioner, but no longer worked clinically.

There were no other employees and no vacancies at the time of our inspection.

The service did not use any bank, agency or locum staff.

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.

All records were electronic. We reviewed four sets of records and saw that they were easily available, clear and completed appropriately. Computers were locked when unattended, to ensure the security of women's notes.

Staff did not have access to the women's NHS medical notes as the women privately self-referred into the service, for an elective boutique service.

The registered manager completed scan reports during the woman's consultation. A print out of their findings and one printed image was given to the woman. A link was sent to the woman's mobile phone which had copies of all images and videos obtained during the scan.

The clinic did not routinely send copies of records to women's GPs. However, if there were concerning results found in a test or scan, a report would be sent to the patient's GP.

No audits were carried out on the completion of records.

Medicines

The service used systems and processes to safely prescribe, administer and record medicines. However, the clinic did not store medicines securely.

Diagnostic imaging

An emergency pack was kept in the clinic which contained adrenaline. It also contained other medicines including lidocaine (a local anaesthetic) which we were told was used when inserting contraceptive coils, as well as other medicines to treat allergic reaction. However, the clinic did not store atropine (a medicine that increases a patient's heart rate if their heart rate drops) or oxygen which were required for women undergoing a contraceptive coil insertion. This was not in line with The Faculty of Sexual & Reproductive Healthcare of the Royal College of Obstetricians & Gynaecologists guidance.

At the time of our inspection, the medicines were not stored appropriately. This meant that women or their relatives could have unauthorised access to the medicines. We escalated this to the registered manager who said they would arrange an alternative method of storing the medicines. Following the inspection, we were provided with evidence that a lockable medicine cabinet had been installed.

Medicines were prescribed for women through private prescriptions. If women were prescribed medicines, a scanned copy of the private prescription was added to the record. The private prescriptions were written on a regular notebook, with the registered manager's General Medical Council (GMC) number added, which showed that it was a valid prescription. These could then be filled at any local chemist. The clinic did not store or dispense medicines on site. Consent to share the prescriptions of medicines with GPs was discussed with women.

Staff checked whether women had allergies prior to prescribing medicines or using certain equipment. An example of this was staff asked if women undergoing a transvaginal ultrasound had a latex allergy, as they used latex condoms to cover the probe. An alternative covering was available for women with latex allergies.

Incidents

Staff recognised incidents and had a form to report them appropriately. There was no formal process to investigate incidents and share lessons learned, although we did see some change to practice as a result of an incident.

There had been no serious incidents or never events at the clinic. Never events are serious, largely preventable patient safety incidents that should not occur if healthcare providers have implemented existing national guidance or safety recommendations.

An incident reporting form was available. However, there was no policy outlining how incidents would be investigated, or any governance processes for the management of incidents. There was no policy outlining the clinic's responsibilities for discharging the duty of candour, although the registered manager was aware of the duty.

We were told one incident had occurred in the 12 months prior to our inspection, which involved a woman who fell on the reception floor. We were told the floor was wet due to recent rain. As a result, staff put a sign on the door warning of a possible slippery floor and bought a mat for the entrance.

Following the inspection, the manager developed a policy covering clinical and serious incidents.

Are diagnostic imaging services effective?

We do not rate effective.

Evidence-based care and treatment

The service did not always provide care and treatment based on national guidance and best practice. Moreover, local guidance was not robust or embedded.

A variety of local guidance and pathways were in place. These covered clinical protocols such as care pathways for insertion of intrauterine contraceptive devices and operational policies on areas including data protection and cleaning procedures. However, we saw that pathways were not always updated when guidance was changed. An example of this was the care pathway for women with menstrual problems. This cited guidance from the National Institute for Health and Care Excellence (NICE) CG44 which was replaced by NICE NG88 in March 2018. The service did not complete audits to confirm compliance with best practice.

Diagnostic imaging

All the policies were amalgamated into one document. This did not have a date that it was written, a date for revision or evidence of review. We raised this as a concern and were told that the clinic would review the policies and instigate version control and review dates. However, we were not provided with evidence of this.

A policy was in place for undertaking anomaly scans. This referenced the measurements to be taken, in line with the NHS fetal anomaly screening programme (FASP) guidelines.

We saw that there was information detailed in the policies that was not embedded. Examples included the framework for clinical governance which outlined mandatory training staff required, when the clinic manager received no training. Other examples included the health and safety prevention and control policy which required cleaning records and checklists to be kept, but the registered manager confirmed no records were kept of cleaning.

Staff ensured women understood that the ultrasound scans performed at the clinic were in addition to those provided as part of their NHS pregnancy pathway and were not designed to replace any NHS care.

The service was inclusive to all pregnant women and we saw no evidence of any discrimination, including on the grounds of age, disability, pregnancy and maternity status, race, religion or belief, and sexual orientation when making care and treatment decisions.

The service made it clear to women that they were not replacing NHS services and that any care provided at the clinic was in addition to NHS provision. As such, women knew that if they had any concerns about their pregnancy or gynaecological health, that they should speak to their GP.

Nutrition and hydration

Staff gave women enough food and drink to meet their needs.

Hot drinks and biscuits were available in the waiting area for women. Although these were on display, we did not see any women being offered these proactively.

Women who were coming to the clinic for ultrasound pregnancy scans were advised to come with a full bladder and ensure they were well hydrated to improve the quality of the scan image.

Pain relief

Staff assessed and monitored women regularly to see if they were in pain, and gave pain relief in a timely way.

Pain relief was available for women having intrauterine contraceptive devices fitted. We saw lidocaine (local anaesthetic) was available for these women. Women were asked during the procedures if they were in pain and if they needed pain relief. The clinic did not use pain scores but asked women if they felt better once the pain relief had been administered. Pain relief was recorded on the woman's record if administered.

Patient outcomes

Staff did not monitor the effectiveness of care and treatment. The clinic collected patient feedback intermittently.

The clinic did not collect any patient outcome data, such as the percentage of gender scans that were correct, the number of rescans that were required or the number of women who had to be referred to another healthcare provider. As such, we were unable to tell what outcomes women had after having treatment at the clinic.

We saw that nuchal translucency scans were audited annually by the Fetal Medicine Foundation. The clinic used software licenced by the Fetal Medicine Foundation and this licence was renewed yearly based on their audit outcomes.

A rescan guarantee was in place, for gender scans and for 3D scans. If the registered manager was unable to determine the baby's gender or get a good image on a 3D scan due to the baby's position, they would offer a rescan at no charge.

We saw staff collected feedback from women occasionally, but there was no schedule to it. However, we noted all feedback was extremely positive. We saw that many patients were return customers or had been referred to the service by a friend or family member.

Competent staff

Diagnostic imaging

The service did not always make sure staff were competent for their roles. Managers did not always appraise staff's work performance.

We saw that the registered manager had competencies and appraisals completed at their substantive NHS post. However, the clinic manager had no evidence of competencies and confirmed that they had not received an appraisal since the clinic was opened in 2011. This was contrary to data provided as part of the Provider Information Return (data requested prior to the inspection) in which it was stated that the clinic manager had received an appraisal. Following us raising concerns, the clinic completed an appraisal for the clinic manager.

As part of our inspection, we reviewed the staff personnel files for the registered manager and clinic manager. We found both had evidence of a disclosure and barring service (DBS) check. DBS checks help employers make safer recruitment decisions and prevent unsuitable people from working with vulnerable groups. There was no evidence of a recruitment and selection interview as both staff members were joint owners of the clinic and had set the clinic up.

The registered manager was registered with the General Medical Council (GMC). We reviewed their entry on the register and saw they were on the specialist register for obstetrics and gynaecology.

Multidisciplinary working

The registered manager and clinic manager worked together as a team to benefit women. They supported each other to provide good care.

The registered manager and clinic manager had a positive working relationship with each other. We observed them working well together to ensure quick flow at the clinic.

The service had established pathways in place to refer women to their GP or local NHS trust if any concerns were identified during their appointment. Staff communicated their referral to the local NHS trust or GPs by letter and telephone.

Health promotion

Staff gave women some practical support and advice to lead healthier lives.

Leaflets were available in reception explaining the benefits of storing stem cells from umbilical cords. Leaflets were also available explaining the benefits of non-invasive prenatal testing (NIPT) which was available at the clinic. This can help identify any genetic or chromosomal disorders early on in pregnancy. There was no information displayed regarding the benefits of exercise or healthy eating, nor the risks of smoking in pregnancy. Following the inspection, we were told that the clinic had access to leaflets online regarding smoking cessation and healthy eating, which they would send to patients if they requested them. However, there was not any promotional materials proactively displayed in the clinic.

Seven day services

Appointments were not available seven days a week. However, the service could flex to meet demand.

The clinic was not open seven days a week as it provided elective planned care, as opposed to emergency responsive care. Appointments were available on Monday evenings, Wednesday evenings, Thursday mornings, Friday evenings and Saturdays. Short notice appointments were sometimes available, depending on the registered manager's availability as they also worked full time as an NHS consultant.

Consent and Mental Capacity Act

Staff did not always support women to make informed decisions about their care and treatment.

Consent was obtained prior to treatments occurring. We saw that implied consent was used for treatments, as they were elective treatments that women self-referred for and paid for. A consent policy was in place. However, this did not reference the Mental Capacity Act 2005 or how a patient's capacity to consent would be assessed.

We observed four scans and saw that the potential risks to the baby from the additional use of ultrasound was not discussed. These were also not displayed on the service's website. As such, we were concerned these women were not aware of the potential risks of additional exposure to ultrasound waves and as such could not provide fully informed consent. This was not in line with the British Medical Ultrasound Society 2016 guidance which stated that all risks and benefits must be discussed.

Diagnostic imaging

We were told by the clinic manager that all women were emailed confirmation of their treatment and its cost prior to the appointment. This ensured women knew how much it would cost prior to entering the clinic. Price lists were also displayed in the clinic waiting area and on their website.

The clinic did not see women aged under 16 years old and therefore, Gillick and Fraser competency (legal tests for determining competency to consent in young people aged under 16) was not relevant.

Are diagnostic imaging services caring?

Good



We rated it as **good**.

Compassionate care

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

Staff were caring with their women and established a positive rapport with them. We saw that women were greeted at reception by the clinic manager and put at ease if they were feeling nervous.

We observed four pregnancy scans during our inspection and saw positive interactions between the registered manager and the women and their relatives. We spoke with two women during our inspection whom were all happy with the service they had been given and told us they would recommend the clinic to their friends and family.

The registered manager ensured the examination room door was shut during treatments to ensure the privacy and dignity of the women.

The staff were very passionate about their roles and were dedicated to making sure women received patient-centred care.

We reviewed a sample of feedback forms and saw all provided positive feedback. Comments included 'we will forever be grateful for the way she handled the hardest news for us to hear' and 'excellent, always polite, friendly and professional'.

Emotional support

Staff provided emotional support to women, families and carers to minimise their distress.

Staff were aware that women attending the service were often feeling nervous and anxious so provided additional reassurance and support to these women.

In the case of abnormal results, for example, a miscarriage, women could remain in the scan room

with their partner or, if they were unaccompanied, call their partner or relative in private. If a scan showed that a woman had miscarried or the pregnancy was non-viable, the clinic used their discretion to waive their fee. The registered manager did not refer patients for any further emotional support but referred them for follow up NHS care.

Understanding and involvement of patients and those close to them

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

Staff explained the care and treatment they were providing to women in easy to understand language. Women we spoke with confirmed this.

The registered manager made sure that women were aware that they still needed to attend their regular scheduled NHS appointments and scans.

Staff had access to a variety of patient information leaflets published by the National Institute for Health and Care Excellence (NICE) which they printed off and talked through with women following a diagnosis.

Are diagnostic imaging services responsive?

Good



We rated it as **good**.

Service delivery to meet the needs of local people

Diagnostic imaging

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

The clinic was located in its own building on the ground floor. The scanning room had an adjustable examination bed, which was used to assist and support women with limited mobility. There was a comfortable waiting area, with drink making facilities and magazines available.

Car parking was available either on the street, or there were several pay and display car parks in the vicinity. Details of these were displayed on their website.

Women were given relevant information about their ultrasound scan when they booked their appointment, such as needing a full bladder.

The service provided payment details in a confirmation email before the woman's appointment. Ultrasound scan prices were outlined on the service's website, with a copy also displayed in the reception area.

The clinic had recently paid for a subscription to an online image storage facility. That meant that following a scan, women received a text message with a link to a website which held all their scan images and videos. Women were then able to use these as they wished, including posting them on their social media.

The registered manager had arrangements in place to contact other healthcare providers, if the outcome of the woman's treatment required this.

Meeting people's individual needs

The service was inclusive and took account of women's individual needs and preferences.

Information leaflets were given to women when they had a pregnancy of an unknown location, for example, an ectopic pregnancy; a second scan that confirmed a complete miscarriage; or an inconclusive scan. The leaflets contained a description of what the registered manager had found, advice, and the next steps they should take.

All scans were undertaken in a private clinic room with lots of space for any additional relatives, friends, or carers to accompany the woman. If a woman was required to undress, locked doors and dignity screens were used to protect her privacy.

All information was displayed in English. All leaflets were printed when needed.

The clinic did not have any information displayed in alternative formats for those with a sensory impairment or additional needs. However, the manager gave an example of using text messaging to cater for deaf patients and we saw that their usual demographic did not usually require additional assistance. We were told the clinic did not cater for women with additional needs, such as a learning disability or those living with dementia.

Access and flow

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

All women self-referred to the service. They could book their appointment in person, by email or by the telephone. Women could pick a time to suit their needs. Same or next day appointments were sometimes available, depending on how busy the clinic was.

At the time of our inspection, there was no waiting list or backlog for appointments. During our inspection, we observed that the clinic ran on time. Waiting times within the clinic were not monitored, however, during our inspection, we observed that the clinic ran on time.

The rates of women not attending their appointments was not formally monitored but we were told that the clinic manager would call women who did not attend appointments, to see if they needed to rebook.

Appointments were available on Monday evenings, Wednesday evenings, Thursday mornings, Friday evenings and Saturdays.

Learning from complaints and concerns

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

Diagnostic imaging

A complaints procedure was in place. This stated that all complaints would be acknowledged within two days and responded to within 20 days.

The clinic had not received any complaints in the 12 months prior to our inspection (March 2019 to February 2020). Part of the reason for this was likely due to their rescan guarantee, whereby if a patient had a 3D or 4D scan and they did not get the quality of images the parents wanted due to the baby's position, they offered additional scans at no cost.

Information on how to make a complaint was displayed in the waiting area and included the Care Quality Commission's contact details.

The clinic was not part of the Independent Sector Complaints Adjudication Service (ISCAS).

Are diagnostic imaging services well-led?

Inadequate 

We rated it as **inadequate**.

Leadership

Leaders had the skills and abilities to run the clinical aspects of the service but did not have an awareness of the governance aspects of managing the clinic. They did not always understand and manage the priorities and issues the service faced.

The registered manager was a qualified consultant obstetrician and gynaecologist, who worked full time clinically in the NHS. As such, they had a strong understanding of the clinical aspects of managing the service. However, they did not have an awareness of all the requirements of being a registered manager, or of the governance aspects required in managing a service.

The registered manager was passionate about the care and treatment they provided women but had not understood or embedded all the requirements needed to keep women safe. Details of these concerns are listed below under 'governance'.

The registered manager was the only person who carried out CQC regulated care or treatment at the clinic.

Vision and strategy

The service did not have a vision for what it wanted to achieve or a strategy to turn it into action.

The registered manager told us they did not have a vision or strategy for how to improve the clinic in the future.

The clinic manager had told us that there were plans for the registered manager to reduce their NHS commitment, to allow more time at the clinic and offer greater flexibility for women. However, the registered manager did not agree with this and stated although there were plans for them to reduce their NHS hours, they would not be increasing the clinic hours.

Culture

Staff were focused on the needs of women receiving care. The service had a culture where women and their families could raise concerns without fear. However, we did not find that the culture of the clinic was open to our concerns.

The registered manager and clinic manager were welcoming and friendly on our arrival. It was evident that they cared about the service they provided and tried to make the experience as happy and positive as possible for the women and their relatives. We saw information was displayed which outlined how women could raise concerns and also provided details of the CQC for them to raise any concerns to.

The provider was aware of the duty of candour regulation but had not had any incidents that met the threshold for implementing the duty of candour.

During the inspection we informed the registered manager of areas of the service that needed improving. Whilst they were receptive to some areas, they did not always respond positively. They stated that they felt the requirements, such as having a risk register, were overly onerous on their clinic. Following our inspection, we sent two emails to the clinic outlining our concerns. These included issues such as the lack of security for medicines, the lack of equipment safety checks and a lack of internal audits, among others. We received responses from the clinic in relation to some of the concerns raised, for example, evidence of new policies being created. However, there were some areas of concern, for example, their medicines management, which were not responded to.

Diagnostic imaging

Governance

Leaders did not operate effective governance processes.

A framework for clinical governance was in place. However, this was not embedded in the clinic, as the registered manager was not sure if it existed until they searched through their computer. Moreover, it was not particularly applicable to the clinic. This was due to the fact that it referenced job roles that the clinic did not have, for example, an operations manager and office and project manager, referenced consultants with practising privileges, for which there were none at the clinic, and referenced a medical advisory committee which was not in place. We raised this as a concern and were told that it had been written when the clinic opened with plans for expansion, but this had not occurred, and the framework had not been updated. We were advised that following our inspection, the framework was reviewed and updated.

The framework also stated that annual appraisals would be conducted, but the clinic manager had not had one since the clinic opened.

We found multiple areas of concern whereby the clinic did not have governance arrangements in place to ensure high standards of care and safety were maintained. These included no cleaning checklists so they could assure themselves the clinic was being cleaned regularly, no records of equipment inspections, and no checklist for checking the emergency pack for its contents and expiry dates.

As highlighted above, in the medicines section of this report, there was also no governance arrangements regarding the medicines in the emergency pack. They were kept in an unlocked box, with no contents list so there was no way for staff to easily tell if an item was missing. Moreover, this box was stored in an unlocked cupboard so anyone could have had unauthorised access to the box, misused the medicines enclosed or removed them.

Similarly, we were not assured the provider had identified what training in key skills the clinic manager needed. They had not received any mandatory training since the clinic opened and the registered manager had to ask what mandatory training the clinic manager required.

We also found that the clinic's policies were not managed appropriately. None of the policies had evidence of when they had been written, when they were due for review or what version of the policy they were. We also found some policies referenced out of date national guidance. We also found areas where there were no policies in place to underpin arrangements. Examples of these included no incident reporting policy, no policy on managing a patient collapse and no policy on adult safeguarding. We raised these as concerns and the clinic sent us copies of policies on adult safeguarding and the management of a patient collapse. Following the inspection period, the service provided us with a copy of an incident management policy.

Managing risks, issues and performance

Leaders and teams did not use systems to manage performance effectively. They did not always identify and escalate relevant risks and issues or identified actions to reduce their impact.

There were no systems in place to manage performance. There were no audits conducted within the clinic to highlight areas of good practice or identify areas of concern. The clinic did not monitor any patient outcomes and therefore, did not have an understanding of their performance.

There were no risk registers or risk assessments in place at the clinic. We identified multiple areas of risk, including hazardous chemicals being stored inappropriately, insufficient governance arrangements for equipment maintenance and the clinic manager having received no mandatory training. None of these areas of risk had been identified by the clinic prior to us alerting them to the concerns.

We raised this as a concern and the clinic sent us a copy of a risk register that they had developed following the inspection. This included risks such as needle stick injuries and body fluid spillage. The risk register included existing control measures and plans to further reduce risk but did not include dates for review. We also saw that risks we identified on inspection as outlined above, were not listed on their risk register.

Managing information

Diagnostic imaging

The service collected reliable data but did not analyse it to understand performance and make improvements.. However, the information systems were integrated and secure.

The clinic did not collect data. As discussed above, the clinic did not conduct any internal audits or checklists, so were unable to analyse performance information. Due to this, they were unable to understand their performance or make any improvements.

At the time of our inspection, the service was not registered with the Information Commissioner's Office (ICO), which was not in line with The Data Protection (Charges and Information) Regulations (2018). The ICO is the UK's independent authority set up to uphold information rights. We raised this as a concern and were informed their registration had lapsed accidentally. Following the inspection, we were provided with evidence that the clinic had re-registered with the ICO.

Women's records were electronic and scan images were easily accessible and were kept secure. Women were sent secure links to their ultrasound scan and videos so they could access them following their appointment.

Engagement

Leaders and staff did not always engage with women to plan and manage services.

We saw that women were sent patient surveys occasionally, but there was no schedule for doing so. We saw copies of surveys were kept by the clinic, and all surveys we saw were complimentary of the service provided. We were told that the clinic also reviewed their feedback through online review websites and social media.

Prices for treatments were displayed in reception and on the clinic's website. However, the terms and conditions associated with payment for treatments were not publicly available on the clinic's website.

We saw no evidence that the clinic engaged with other organisations to plan or manage their regulated activity.

We saw that there was strong engagement and a positive working relationship between the registered manager and clinic manager. They engaged well with each other and the women they saw in the clinic. We observed positive rapports between staff and women during the inspection.

Learning, continuous improvement and innovation

The registered manager was not always committed to continually learning and improving services. They did not have a good understanding of quality improvement methods and the skills to use them.

There were examples of staff being committed to improving services. Examples of this included them buying a new ultrasound machine as they were aware that technology had improved since they had bought theirs and that newer machines gave better image quality. However, during our inspection we also found that the clinic was not always receptive to the concerns we raised in relation to regulatory compliance.

Our interviews with staff demonstrated a lack of commitment to improving in these areas. Following our inspection, the provider made some improvements, however, these are yet to be embedded.

Outstanding practice and areas for improvement

Areas for improvement

Action the provider **MUST** take to improve

- The provider must ensure that governance arrangements are in place to ensure that risks are adequately identified and mitigated, the quality of the service is monitored, and appropriate policies are in place and maintained (regulation 17 (2) (a) (b) (d) (ii))
- The provider must ensure that infection control procedures are adhered to, that appropriate records are kept in relation to infection control and that hazardous chemicals are stored correctly (regulation 12 (2) (h))
- The provider must ensure that all staff complete mandatory training, including safeguarding training and have an appraisal (regulation 18 (2) (a))
- The provider must ensure that all women are given all the risks and benefits of any treatment, before undergoing it, so that they can give fully informed consent (regulation 9 (3) (c))

Action the provider **SHOULD** take to improve

- The provider should consider that health promotion materials are available to educate women on healthy lifestyles.
- The provider should consider that information is available in languages other than English.
- The provider should consider creating a vision and strategy.
- The provider should consider recording visual maintenance checks of equipment.
- The provider should ensure that processes are in place to ensure compliance with the General Data Protection Regulation. (regulation 17)
- The provider should ensure arrangements are in place for women to access appropriately trained chaperones. (regulation 13)

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 Treatment of disease, disorder or injury	Regulation 12 HSCA (RA) Regulations 2014 Safe care and treatment How the regulation was not being met: We were not assured that medicines were being managed safely. (regulation 12 (2) (g)) We were not assured that cleaning chemicals were stored appropriately or that cleaning schedules were robust. (regulation 12 (2) (h))
Regulated activity	Regulation
Diagnostic and screening procedures Treatment of disease, disorder or injury	Regulation 18 HSCA (RA) Regulations 2014 Staffing How the regulation was not being met: We were not assured that staff completed mandatory training or received an appraisal. (regulation 18 (2) (a))
Regulated activity	Regulation
Diagnostic and screening procedures Treatment of disease, disorder or injury	Regulation 9 HSCA (RA) Regulations 2014 Person-centred care How the regulation was not being met: Women were not told of the potential risks of additional ultrasound prior to their scan occurring. (regulation 9 (3) (c))

This section is primarily information for the provider

Enforcement actions

Action we have told the provider to take

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

Regulated activity	Regulation
Diagnostic and screening procedures	<p>Regulation 17 HSCA (RA) Regulations 2014 Good governance</p> <p>How the regulation was not being met:</p> <p>We were not assured that risks to the service were identified or monitored. (regulation 17 (2) (b))</p> <p>We were not assured that the quality and safety of the service was monitored. (regulation 17(2) (a))</p> <p>We were not assured that policies were robust and there were areas of practice which were not supported by a policy. (regulation 17 (2) (d) (ii))</p>