Early Life Ultrasound Centre

Quality Report

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This report describes our judgement of the quality of care at this location. It is based on a combination of what we found when we inspected and a review of all information available to CQC including information given to us from patients, the public and other organisations

Ratings

Overall rating for this location	Good
Are services safe?	Good
Are services effective?	
Are services caring?	Good
Are services responsive?	Good
Are services well-led?	Requires improvement

Summary of findings

Letter from the Chief Inspector of Hospitals

Early Life Ultrasound Centre in Cheltenham, is operated by Early Life Ultrasound Centre Limited. Scans are provided for pregnant women from 16 years of age. The service provides a range of scans for pregnant women with scans taking place from seven weeks to full term. The service is provided to self-funding women across Cheltenham. These include, 3D/4D ultrasound imaging, early pregnancy/reassurance scans, endometrial lining scans and well-being scans.

The service also provides non-invasive prenatal testing (NIPTs) for pregnant women and caters for pregnant women who choose obstetric ultrasound services, in addition to routine antenatal ultrasound services or those who are undergoing fertility treatment abroad.

All women accessing the service are seen as private (self-funding) patients.

The service provides the single specialty core service diagnostic imaging. We inspected this service using our comprehensive inspection methodology. We carried out a short notice announced inspection on 8 January 2020.

To get to the heart of patients' experiences of care and treatment, we ask the same five questions of all services: are they safe, effective, caring, responsive to people's needs, and well-led? Where we have a legal duty to do so we rate services' performance against each key question as outstanding, good, requires improvement or inadequate.

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

We rated it as **Good** overall.

We found the following areas of good practice:

- Staff had the right qualifications and skills, received and completed mandatory training.
- Staff understood how to protect people from abuse and report incidents.
- The service had suitable premises and equipment.
- The service assessed and responded well to patient risk.
- The service followed national guidance, and staff followed consent legislation to make sure they were meeting the needs of the women who used the service.
- Providing a positive experience for women was central to the service. Staff cared for women and those close to them with compassion, kindness, dignity and respect. Staff provided emotional support to women and those close to them to minimise their anxiety.
- Staff involved women and those close to them in decisions about their care and treatment.
- The service was responsive to the needs of women and their families and was tailored to pregnant women. People were able to access an appointment when they needed it.
- There was a vision for what the service wanted to achieve, and a positive culture was promoted that supported and valued staff. The service also engaged well with women and their families.
- The service had a system to identify risks and controls to reduce them, and cope with both the expected and unexpected.

However, we found the following areas required improvement

- Improvements were needed to some areas to control the risk of infection.
- The registered manager needed to familiarise themselves with the duty of candour regulation.
- We were not assured that policies were regularly reviewed and updated.
- There was a lack of documented evidence in appraisals to demonstrate discussions around performance or future development.

Summary of findings

- Governance processes needed to be strengthened to enable the service to systematically improve service quality and safeguard high standards of care.
- The service did not adhere to Schedule 3 of the Health and Social Care Act to ensure safe recruitment.

However,

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 two requirement notices. Details are at the end of the report.

Dr Nigel Acheson
Deputy Chief Inspector of Hospitals (South)

Summary of findings

Our judgements about each of the main services

Service	Rating	Summary of each main service
Diagnostic imaging	Good 	This is a diagnostic imaging service run by Early Life Ultrasound Centre Limited. The service is based in Cheltenham. We rated the service as good. Safe, caring and responsive were good but well led required improvement. We do not rate effective for this type of service.

Summary of findings

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Good

Early Life Ultrasound Centre

Services we looked at
Diagnostic imaging

Summary of this inspection

Background to Early Life Ultrasound Centre

Early Life Ultrasound Centre is operated by Early Life Ultrasound Centre Limited. We previously inspected this service in September 2013, where it met all of the standards it was inspected against.

The registered manager had held their post at the service since January 2013. The service is registered to provide diagnostic and screening procedures regulated activity at the location.

Our inspection team

The team that inspected the service comprised of one CQC inspector. The inspection team was overseen by Amanda Williams, Head of Hospital Inspection for the South West.

Information about Early Life Ultrasound Centre

Early Life Ultrasound Centre is a small service, running clinics six days a week in the mornings and evenings. The service offers:

- Early pregnancy scans from seven weeks
- Gender scans from 16 weeks
- 3D and 4D scans that include well-being and growth checks
- Well-being scans for those who have an interest in souvenir imaging
- Non-invasive pre-natal testing (NIPTs)

The prenatal test is a type of non-invasive prenatal screening. It looks at fragments of the baby's DNA in the woman's blood to provide accurate information about the likelihood for the most common chromosomal conditions from as early as 10 weeks gestation.

Facilities included a scan room containing one ultrasound machine, a reception and waiting area.

During the inspection we visited the clinic and spoke with three staff including the registered manager, a sonographer and a receptionist. We spoke with one patient. We reviewed 12 sets of patient records and relevant policies and documents.

We reviewed data submitted as part of the Provider Information Request. Data covered the last 12 months between September 2018 to September 2019.

There were no special reviews or investigations ongoing by the CQC at any time during the 12 months before this inspection.

Activity between 1 January 2019 to 31 December 2019

- 2,213 appointments
- Of these 2,210 appointments, 643 were early pregnancy scans, 794 were gender reveal scans, wellbeing scans 159, 3D/4D 526 and endometrial lining scans 26.
- 66 NIPTs
- 121 cancellations

Track record on safety between September 2018 to September 2019

- Zero never events
- Zero clinical incidents
- Zero serious injuries
- Zero incidences of hospital acquired infection
- Zero complaints

Services provided under service level agreement:

- Maintenance of scanning equipment by the manufacturing company.
- Sharps and clinical waste removal.

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?

Good

We rated it as **Good** because:

- The service provided mandatory training in key skills to all staff and everyone completed it.
- Staff understood how to protect people from abuse and the service worked well with other agencies to do so.
- Care pathways supported staff to identify and quickly act upon women at risk of deterioration.
- The service had enough staff with the right qualifications, skills, training and experience.
- Records were complete and stored securely.

However:

- Improvements were needed to some areas to control the risk of infection.
- There was no date or signature to indicate when sharps boxes were first used
- There was a lack of understanding around the duty of candour regulation.

Are services effective?

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

- We were not assured policies were regularly reviewed and updated.
- There was a lack of documented evidence, in appraisals, to demonstrate discussions around performance, future development and the induction process.

However:

- The service provided care and treatment based on national guidance.
- Drinks were offered to women and their families attending the service.
- Staff worked together as a team within the clinic to benefit women and their families.
- Staff supported patients to make informed decisions about their care and treatment. They followed national guidance to gain patients' consent.

Summary of this inspection

Are services caring?

Good

- Staff cared for patients compassionately and treated them with dignity and respect.
- Staff provided emotional support to women to minimise their distress and anxiety.
- Staff involved women and those close to them in decisions, their care and treatment.

Are services responsive?

Good

- The service planned and provided services in a way that met the needs of local people. There was a wide range of services and appointments for women to access throughout all stages of their pregnancy.
- The service took account of women and their families individual needs.
- People could access the service when they needed it.
- There was a system to manage complaints.

Are services well-led?

Requires improvement

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

- Governance processes needed to be strengthened to enable the service to systematically improve service quality and safeguard high standards of care.
- There was no programme of audit to identify how the service was performing and to identify areas for improvement.
- Records were not always maintained around the monitoring the effectiveness of service delivery.
- The service was not compliant with Schedule three of the Health and Social Care Act.

However:

- The service had a vision for what it wanted to achieve.
- A positive culture was promoted that supported and valued staff, creating a sense of common purpose based on shared values.
- The service engaged well with women and their families and used feedback to improve the service. It was committed to improving services by learning from when things went well, or wrong.

Detailed findings from this inspection

Overview of ratings

Our ratings for this location are:

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

Good

Diagnostic imaging

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

Are diagnostic imaging services safe?

Good

We had not previously rated safe. We rated it as good.

Mandatory training

- **The service provided mandatory training in key skills to all staff and made sure everyone completed it.**
- Mandatory training covered topics such as infection control, safeguarding, mental capacity training, DoLS, first aid, health and safety, equality and diversity and fire protection.
- Records confirmed all staff were up to date with their training. An electronic training log had been set up for each employee recording the date when training and updates were completed. The log sent an email to the registered manager when training was due to be updated.
- Staff who carried out the non-invasive prenatal testing (NIPTs) had all received mandatory training. This was provided by a charity that specialised and supported families and healthcare professionals in prenatal testing and its outcomes.
- Mandatory training was done both face to face and via e-learning. Staff told us training was good quality, useful and supported them in their roles.

Safeguarding

- **Staff understood how to protect people from abuse and the service worked well with other agencies to do so.**
- A safeguarding policy was available for staff to access. The policy outlined the role and responsibilities of the registered manager and action staff must take should they have concerns about a child's or adult's safety and welfare. The policy identified the local authority to be informed. However, the policy did not contain the telephone numbers to be used if this situation arose. Referrals would be made to the local authority by the safeguarding lead for the service.
- A sonographer was service lead for children and adults safeguarding. This member of staff had completed safeguarding level three in October 2019. There had been no requirement for the service to make any referrals to the local safeguarding teams.
- The service were aware of their role and responsibilities around safeguarding. The service had recently been included in an external safeguarding case, identified by another party. A member of staff also confirmed they knew how to make safeguarding referrals.
- All staff received safeguarding training for children and adults to a minimum level two. There was full compliance with this training.
- All staff had completed a course on female genital mutilation, in October 2019, to raise awareness about this issue. However, the safeguarding policy did not include information or guidance for staff on female genital mutilation or child sexual exploitation. Following the inspection, we were told this information had been added to the policy.

Cleanliness, infection control and hygiene

- **Improvements were needed to some areas to control the risk of infection. Staff were not always bare below the elbow and no infection control audits were carried out to ensure compliance with policies and procedures.**

Good

Diagnostic imaging

- The registered manager and one of the administration staff were the infection control leads. An infection control policy was operated to ensure the premises was safe and clean and that staff maintained standards of cleanliness and hygiene with regards to handwashing. Staff undertook infection control training, and there had been no incidences of healthcare acquired infection in the last 12 months. All staff had completed mandatory training in infection control.
- Sonographers were observed using hand gel to clean their hands before each scan to reduce the risk of cross contamination. There was no handwashing sink in the scan room, although staff had access to a sink in the staff toilet. However, we observed on one occasion a member of staff was not bare below the elbow as set out in the policy.
- The probe of the scan machine and couch was cleaned after each use, using wipes provided, in line with best practice and the policy.
- Personal protective equipment, for example gloves and aprons, were available to staff if required.
- There were arrangements to reduce risk of exposure to blood-borne viruses (BBV). This was covered in the services infection control policy. Blood spill kits were available on the premises in case of spillage. The policy outlined the safe procedure which staff followed when using the kits. However, the blood spill kit went out of date in 2018. The registered manager stated that the laminate flooring which had been recently introduced now mitigated the need for the blood spill kit, as the flooring could be disinfected. We saw evidence following the inspection that a new blood spill kit had been purchased.
- Staff were trained in taking blood and the management of blood as part of the NIPT screening. While we did not observe this in practice, a member of staff told us how they did this to reduce the risks of cross infection, for example, wearing gloves.
- A fabric tourniquet was used to compress the arm when taking blood fabric tourniquets are not recommended for use in clinical areas due to the infection control risk. This is because the fabric was not wipeable or single use, meaning blood or bacteria could remain on the tourniquet and be transferred to other patients. Following the inspection, we were provided with evidence to show the fabric tourniquet had been replaced following our inspection.
- The premises were kept clean to reduce the risk of infection and cleaning schedules were used. Daily and weekly cleaning checklists were used and checks had been completed for six months prior to our inspection. The area was visibly clean and free from dust.
- Cleaning products and equipment were not locked away and stored securely at the time of our inspection. There was a small risk that these could be accessed by children attending the service. Guidance from the Health and Safety Executive: Storing chemical products (small scale) states that these should be kept locked away. However, we saw evidence that this was rectified by the service immediately post inspection.
- A Control of Substances Hazardous to Health (COSHH) risk assessment had been completed for the service. There was evidence that this risk assessment had been updated in December 2019 to include a risk assessment for the cleaning product used to clean the new flooring in the scanning room.
- An infection control statement had been completed in September 2019. This covered the purpose of the statement, the role and responsibility of the infection control lead, significant events, audit, staff training and policies and procedures. The statement identified that an internal audit had been completed to ensure adherence to the code of practice, with several actions identified as a result. These included actions such as allocating a named infection control lead, infection control being a regular agenda item at monthly team meetings, reviewing infection control policies and environmental cleaning audits carried out by staff.
- We saw evidence that staff completed cleaning checklists. However, we did not see documented evidence of how these were used to audit the adherence to the infection control policy. We saw that infection control was on the agenda for the November 2019 team meeting. However, the content only made reference to cleaning schedules being checked and completed.

Environment and equipment

- **The service had suitable premises and equipment. However, there was no documented system to evidence when equipment maintenance was required.**
- The service had suitable facilities to meet the needs of patients and their families. There were seating areas for

patients to wait which were not visible to people walking by the street window. There was a toilet available, with baby changing facilities, for women and visitors to use.

- There was adequate storage of consumables. These were stored tidily in cupboards to make the environment clutter free. NIPTs packs containing blood sample bottles were in date.
- The service used latex free covers for the transvaginal probe in case a woman was allergic to latex. Latex free gloves were also used.
- There was system to support the maintenance of equipment. The registered manager knew the dates when equipment maintenance and portable appliance testing (PAT) testing was required. All PAT testing was in date. Following the inspection, the registered manager told us dates for equipment maintenance were recorded in the electronic booking calendar.
- Equipment was serviced and maintained in line with manufactures guidance, although there had been challenges to schedule the annual maintenance of the ultrasound machine. The registered manager told us equipment was serviced and maintained on a yearly basis. The ultrasound was out of date by a couple of months. We saw an email trail to the manufacturer prior to the machine requiring servicing, where the registered manager had tried to book the machine in for servicing. This had run over the required date due to challenges to get an engineer to come and service the machine. A date had been made for February 2020 and we saw evidence following the inspection that this had been carried out.
- There were arrangements for disposal of any clinical waste and sharps. The service had a service level agreement with a company to remove clinical waste and sharps bins.
- Staff carrying out NIPTs were familiar with the process for disposing of sharps and sharps bins were stored securely when not in use. This was also outlined in the infection control policy. Despite sharps bins not being overfilled, there was no date or signature to indicate when sharps boxes were first used. The Health Technical Memorandum 07-01: Safe management of healthcare waste, advises that sharps bins should be labelled on assembly to ensure that they are collected and disposed of safely, three months after they were initially opened.
- The environment was appropriate for taking blood. Blood was always taken in the designated phlebotomy chair. This meant women were in a supported position to make the experience as comfortable as possible. The chair was made of a material that could be wiped clean to prevent the spread of infection.
- There was a process to label, store and send blood samples away for processing. All of the equipment came as part of an individual pack for each test carried out. The packaging adhered to the Royal Mail's P650 Packaging instruction for diagnostic specimens. This meant that non-invasive prenatal testing (NIPT) samples were sent securely to the laboratory in London.
- An air conditioning unit had been installed in the premises in summer 2019 to ensure the comfort of women and their families when visiting the service during periods of hot weather.

Assessing and responding to patient risk

- **Pathways supported staff to identify patient risk and the service quickly acted upon women at risk of deterioration.**
- There had been one patient who had been urgently transferred from the location to the local NHS trust in the last 12 months; this occurred in March 2019. The service's policy was followed, and the patient was successfully treated at the local NHS trust. The patient record provided an account of the actions taken by the service to ensure the safety of the woman. We saw evidence that a verbal handover over the telephone was provided to the NHS healthcare professional. The woman also took a copy of the scan record for the hospital.
- All of the scans, other than the 3D and 4D scans, included a wellbeing check of the baby. Any abnormalities would be referred to the women's midwife to follow up.
- There was a process to escalate unexpected or significant findings if a scan identified an anomaly, that in the sonographer's professional opinion required medical care. The patient would be referred to their local NHS, GP or midwife. Staff had access to a flow chart/pathway to support the onward referral of patients where scans identified concerns which required further investigation.
- Women were required to identify risks from previous pregnancies, such as miscarriages, ectopic pregnancies and other associated problems, on the form they consented to the scan. This alerted sonographers of any previous risk factors or factors which may make the

women at higher risk for their pregnancy. Women were also asked the date of their last menstrual period to make sure they were at least seven weeks pregnant when they attended for a scan. This information was only discussed and referred to if needed during the appointment.

- There was a system to ensure people received care quickly if an emergency situation arose. There was a Medical Emergency Policy and Procedure available for staff. This set out the actions which staff should take if and emergency situation occurred. The policy required staff to call 999 so the patient could be taken to a local accident and emergency department at an NHS trust. Staff were aware of the actions to take if a patient deteriorated. They were able to give us examples of how they had managed certain situations which had arisen during appointments.
- There was a procedure to follow to ensure women had timely access to the fetal medicine team at the local NHS trust if their non-invasive prenatal testing (NIPT) identified any risk. In the event of a high probability test, following the NIPT testing, the service sought consent to share the information with the fetal medicine team to get ongoing care and support from the most qualified team to manage the concerns in the NHS.
- The service had a procedure for staff to follow in the event of detecting either a suspected or confirmed ectopic pregnancy. The policy for emergency referral in suspected or confirmed ectopic pregnancy identified action the staff must take in different scenarios. Staff were to either call 999, in the event of significant concern, or refer to anearly pregnancy assessment service, or out-of-hours gynaecology service in the event of specific signs being present on examination. The policy contained the telephone number and the direct pager number for the team based at the local NHS trust. Staff provided an example of when this had occurred, and records confirmed action had been taken in accordance with the policy and procedure.
- Disclosure and Barring Service (DBS) checks were completed for all staff. The registered manager maintained a record of each DBS certificate number and the date the check had been completed.
- The service was clear with women that the scans provided were to be regarded as additional scans to their routine scans carried out under the NHS. This information was clear on the service's website and was also reinforced by the sonographers following the women's appointment. This information was also highlighted on the consent form signed by women.
- The registered manager ensured staff carrying out NIPTs had been immunised against Hepatitis B. This was in line with the services policy.

Staffing

- **The service had enough staff with the right qualifications, skills, training and experience to keep people safe from avoidable harm and to provide the right care and treatment.**
- The service was fully staffed and there were no staffing vacancies. No staff had joined or left the service in the year prior to our inspection.
- There were two sonographers working part-time for the service. One of the sonographers also held the registered manager role. Both were accredited through the Consortium of Accredited Sonography Education (CASE). There were five part-time administration staff. The registered manager was registered under the Society of Radiographers as a sonographer. The other sonographer was planning to undertake further study to meet the criteria to be registered by the Society of Radiographers.
- The Staffing Levels and Rota policy ensured that rotas provided adequate staffing cover. Rotas were arranged three months in advance and planned around the specific days assigned to each staff member to provide cover. Flexibility was provided in-house by the staff to ensure cover if staff were unwell or on annual leave. Staff told us that in times of need sonographers would also carry out administration duties.
- Staff did not work alone, so there were no risks associated with lone working. The Staffing Levels and Rota policy stated a minimum of one sonographer and one administration member of staff would be working at any one time. If staff were alone in the clinic room they could always summon help from the administration staff, for example, if a woman became unwell.

Records

- **Staff kept records of patients' care and treatment.**

Good

Diagnostic imaging

- Paper records were kept for each woman who attended for a scan. They were also given a copy to keep and were explained to the women and their families before leaving their appointment.
- Sufficient information was obtained and recorded prior to the scan, for example pregnancy history and health. Patient names were recorded on the scan machine along with the last menstrual period to calculate the expected number of weeks pregnant, prior to performing the scan.
- Women were required to bring their antenatal notes into the clinic. Information on the services website reminded women to bring this information to their appointment. These were not referred to unless there was a problem identified at the start or during the scan.
- Records were stored securely. Current records were held in a file behind the reception desk, which was manned at all times. Archived records were kept in a locked cupboard. Data retention was addressed in the service's records policy.
- We reviewed 12 records for the service. All seven records for scans we reviewed contained a signed consent form, with the ultrasound reports all being completed. Records identified the type of scan and reason for scan, the observations from the scan and a forward plan. We reviewed records for five women who had attended for NIPTs appointments. These records including the checklist and the consent forms were also fully completed.
- When patients were transferred to the local NHS supporting information was also sent. Women were provided with a copy of their reports which they gave to the healthcare professional when they were referred, following identification of an anomaly.

Medicines

- The service did not store or administer any medicines.

Incidents

- **The service had processes for reporting and managing patient safety incidents. However, there was a lack of clarity around the duty of candour regulation.**
- The was an accident and incident reporting system and policy. There had been no incidents reported for the service in the last 12 months prior to our inspection, therefore we were unable to review the process.
- There were processes to record the incident within an incident book and the registered manager was responsible for investigating and sharing learning or informing staff of a change. Staff were clear on the incident reporting process and what they would report.
- There had been no serious incidents reported in the last 12 months prior to our inspection date.
- Duty of candour is a regulatory duty that relates to openness and transparency. It requires providers of health and social care services to notify patients (or other relevant persons) of certain 'notifiable safety incidents' and provide reasonable support to that person. The service had a duty of candour policy which set out the role and responsibilities of the staff and registered manager. During a discussion, the registered manager had a basic oversight of the principals of duty of candour but lacked clarity around its application. The registered manager was candid about saying they would have to refer to the policy as they had not had to apply the duty of candour and could not remember. No duty of candour notifications were required to be made in the last 12 months prior to our inspection date.
- The registered manager was aware of the requirements for reporting incidents and submitting notifications to the Care Quality Commission and other regulatory bodies. However, this had not been required in the year prior to our inspection.

Are diagnostic imaging services effective?

We do no rate effective for this core service.

Evidence-based care and treatment

- **The service provided care and treatment based on national guidance and evidence of its effectiveness. However, we were not assured that policies were regularly reviewed and updated.**
- Guidelines were followed for professional ultrasound practice from the British Medical Ultrasound Society (BMUS). Clinical procedures were outlined within the protocols and procedures handbook and were in line with guidance from the National Institute for Health and Care Excellence. Clinical procedures consisted of

algorithms for clinical pathways, tailored for private clinic use. Examples of clinical pathways used included the incidental test finding pathways and the Harmony Test pathway (NIPT).

- The service used ectopic pregnancy and miscarriage: Diagnosis and initial management in early pregnancy of ectopic pregnancy and miscarriage, National Institute of Clinical Excellence clinical guideline 154 (2012) to ensure women received timely care and treatment from the most appropriate healthcare professional if this situation occurred. Guidelines and algorithms for staff to follow were available in the scan room.
- It was unclear whether policies were regularly reviewed and updated. There was no documented evidence on the policy to show when the policy had been developed and when reviews had taken place. Policies did not contain a version control history. Staff had access to policies electronically. We saw evidence that staff were made to sign to identify they had re-read the services policies on a yearly basis. We also saw evidence that the registered manager received emails from BMUS regarding best practice and updates. The registered manager told us they would also circulate any changes in policies to staff via their social media chat group. Following the inspection, we were told that dates, review dates, versions and updates had been to current policies
- There was no audit programme to assure the compliance of the staff with the policy and procedures.
- Best practice guidelines were followed. For example, scans were conducted according BMUS recommendations for 'As Low As Reasonably Achievable' (ALARA) principles for safety in ultrasound scanning; for length of scan and frequency of ultrasound waves. The service's website provided written information for women attending the service and links to further information, should the women want further information. The consent form signed by women also included information about what ultrasound was and its limitations. Public Health England (PHE) guidance advises that although there is no clear evidence that ultrasound scans are harmful to the fetus, parents-to-be must decide for themselves if they wish to have ultrasound scans. During the inspection we observed the sonographer provide clear information and signposting, so the woman could make an informed decision whether to return to the clinic later in pregnancy for a further scan.

Nutrition and hydration

- **Drinks were offered to women and their families attending the service.**
- There was a drinking water dispenser in the waiting area, which was accessible to women and visitors, along with a coffee machine offering different coffees. Tea and herbal tea were also available. There were cartons of orange juice available for children attending the service. We saw the member of staff on reception offering people drinks and making them.

Pain relief

- Pain was not formerly monitored, as this was not required for the service provision. However, staff were observed making sure women were comfortable during their scans.

Patient outcomes

- **Staff monitored the effectiveness of care and treatment.**
- Activity for the service was held electronically in the services booking system. This captured service activity, such as number of appointments made.
- The registered manager could access data referring to the number of scans performed, the type of scan performed, and how many NIPT tests completed. They could also access the number of cancellations and the reason for cancellation. The registered manager told us they monitored and reviewed the data.
- There was a formal process to record the number of women who had been referred to either the local NHS hospital, GP, or their midwife which we reviewed for 2019.
- Sonographers were fully qualified in identifying an anomaly and how to conduct a referral to the NHS and there were clear pathways to do this.
- Although comprehensive and thorough assessments were carried out by the service around patient outcomes, audits were not completed to review compliance with NIPT testing in accordance with the laboratories guidance and the services own policies. The registered manager also explained that the sonographers routinely looked at adnexa (the adnexa means the parts adjoining an organ) during early scans. It was important to examine the adnexa to identify if there was any pathology that could cause risk or harm

to the mother or baby. There was no audit to demonstrate that this was being done and reported on, to demonstrate that the service was in fact providing a high-quality effective service for women.

Competent staff

- **Although it was clear staff were competent in their roles, there was a lack of documented evidence in appraisals to demonstrate discussions around performance, future development or documented evidence of what the induction process covered.**
- Annual appraisals were completed for staff. All staff including the sonographers and administration staff had received an appraisal. We reviewed five appraisals. The appraisal form used a numerical scoring system to review aspects of practice. We found evidence of documented feedback from the appraiser on only one staff member's appraisal. There was no documented evidence to support the numerical ratings on the appraisal form or to evidence any discussions which were held about current performance or future development. The appraisal process was due to be completed and held electronically from 2020. This record required more written content which would improve the process.
- There was no formal record to evidence that staff had received an induction and what this covered. We were told all staff received an induction. We were shown evidence that a member of bank staff had spent three days shadowing another member of the administration team on starting at the service. However, nothing had been formally documented to identify what had been covered across these three days to ensure they were competent in their role.
- A three monthly peer review process occurred between the sonographers to review the quality of the service being provided. This was completed using the British Medical Ultrasound Society recommended peer review checklist. We saw how the process had raised a suggestion from one member of staff for the other to take into consideration for future practice.
- Staff who took blood to carry out NIPTs received training to ensure they were competent to carry out this role. All members of staff who carried out the NIPT tests had completed a training course with a registered charity who specialised in supporting healthcare professionals and women and their families with pre-natal testing and its outcomes. The training course attended covered communication skills, delivering bad news and the implications of antenatal screening and its outcomes. Staff had completed phlebotomy training and subsequent yearly sharps training course to maintain their competency to carry out this test.
- The registered manager had completed postgraduate training in medical ultrasound. This provided them with additional skills to use when performing ultrasound scans on women.
- One of the sonographers was looking into completing level seven of their studying with the Consortium of Accredited Sonography Education (CASE). They hoped to undertake this in 2020.

Multidisciplinary working

- **Staff worked together as a team within the clinic to benefit women and their families. The service communicated with other healthcare professionals as required.**
- There was a clear pathway to communicate with the fetal medicine department at the local NHS trust when a concern was identified. The policy and flow chart was available for staff to refer to. The service had the contact details for the local NHS trust, including the out of hours gynaecology service and direct contact details for registrars on call, when a discussion was required. We saw evidence of a verbal handover provided to the NHS clinicians on one occasion.
- The service liaised with other healthcare professionals outside of the NHS trust when required the local NHS trust. The service advised women to contact their midwife or GP, when required, following the outcome of a scan. Women made their own referrals to their GP and midwives. The registered manager told us it was easier for the woman to do this rather than the service due to the challenges of getting to speak to someone. The registered manager told us that they would contact the woman to make sure they had made the referral. Documented evidence of this was inconsistent as discussed under the records section.
- During the inspection we observed the team working well together to deliver the service. They communicated clearly with each other. They told us that they were a close, supportive team.

- The service used a portal to communicate with the laboratory for NIPT testing. An email notification would advise them to access the portal and view the updated results. This meant the woman could be contacted in a timely manner and referred on as required.

Seven-day services

- **The service was provided six days a week. This included weekdays, and weekends.**
- The service was open across a range of times to ensure women could attend an appointment which suited their needs. The clinic provided morning sessions on four days of the week. Evening sessions from 6.30pm to 9pm were available three days a week and the service opened all day on Saturday. This enabled women who worked full-time to access the service at their convenience.

Health promotion

- **Health promotion for women at all stages of pregnancy was considered.**
- The service worked with a charity who support women throughout their pregnancy and beyond. The packs given to women at the end of their appointment were designed for women in their third trimester of pregnancy and contained valuable information from common occurring symptoms, abbreviations in medical notes, antenatal schedules to healthy eating and smoking cessation.
- The service provided information for women and their families for the promotion of self-care who were in the early stages of pregnancy. There were also leaflets available on domestic abuse and post-natal depression. Although there was no information for women about smoking cessation or alcohol consumption, we were told following the inspection that information had been ordered so it was available for women attending.

Consent and Mental Capacity Act

- **Staff supported patients to make informed decisions about their care and treatment. They followed national guidance to gain patients' consent.**
- Staff completed training in relation to consent, and the Mental Capacity Act (2005), as part of their mandatory training programme.
- There was a Consent to Examination policy covering the consenting process, which occurred prior to the examination commencing. Women's consent to care and treatment was sought in line with legislation and guidance. All women were required to complete a consent form prior to undergoing ultrasound scanning. Consent form information included terms and conditions, such as scan limitations, referral consent, and use of data.
- Of the 12 records we reviewed, consent processes were complete for all women attending the service.
- The Harmony Checklist for NIPT testing was used with women requesting this service. The checklist was a way to ensure that women and their families understood the nature of the test, its limitations and what would happen in the event of a high probability test. This ensured that women were fully informed to consent to the screening assessment and potential outcomes.
- The consent to examination policy also set out the consenting process and referred to the Gillick competence when a young person, either 16 or 17 years of age, attended the service. Where appropriate, the service would look to identify whether the child understood the information being given to them to identify Gillick competence to make decisions. One member of staff we spoke to was clear about Gillick competence and its principals. There had only been three people between the age of 16 and 17 years attend the service in the year prior to our inspection.

Are diagnostic imaging services caring?

Good

We had not previously rated caring. We rated caring as **good.**

Compassionate care

- **Staff cared for patients compassionately and treated them with dignity and respect.**
- The service was committed to delivering the highest level of care and customer service to women and their families to provide the best experience for them. Staff took the time to interact with patients and their families in a respectful and considerate way.
- It was clear staff were keen to create a welcoming and relaxed environment. Patients and their families were greeted in a friendly and welcoming manner. From

entering the service women and their friends and family were subject to a private, calm environment which and the service made sure everyone felt included and part of the experience.
- Staff demonstrated a passion and enthusiasm for the service. All the staff from the service had been previous service users or family members of service users at one time.
- Privacy and dignity was maintained for women. There was a small changing area covered by in curtains the scan room. The service provided a robe for women to wear if they wished and ensured they were covered with a towel to maintain their dignity at all times if they were required to undress for a transvaginal scan. There were blinds in the waiting room which meant patients were not seen from the road, helping to maintain their privacy and confidentiality.
- Feedback to the service was on the whole consistently positive. Women said, 'staff put my mind at ease,' 'lovely staff,' 'grateful to have this beautiful experience with you,' and 'such a kind welcome.'

Emotional support

- **Staff provided emotional support to women to minimise their distress and anxiety.**
- We did not see any examples of difficult information or findings being communicated to women and their families. However, staff spoke about different ways they would communicate bad news to women. This included face to face or over the telephone. This gave women a choice as to what would be best for them. Information was provided to women as to where they could access support if needed.
- Staff showed empathy for patients. As part of their NIPT training, staff were trained on the emotional aspects of receiving bad news. Women were offered a card with contact details for The Miscarriage Association, along with other information so they could seek support and advice.
- Staff recognised women and their families could be anxious when attending early pregnancy scans. One patient openly told the sonographer she was anxious. The sonographer spent time putting the woman at ease, providing reassurance and explaining things to her. Following the appointment, the woman told us that she was put at ease and had come away feeling reassured.

Understanding and involvement of women and those close to them

- **Staff involved women and those close to them in decisions and their care and treatment.**
- Staff communicated with women and those accompanying them in a way they could understand. We heard staff use language and terms women could understand when performing the scan.
- Staff made sure women understood their report before they left their appointment. Staff took the time to explain the findings of the report again to women once this had been printed for them and gave the women an opportunity to ask further questions if they so wished.
- The 30-minute appointments allowed plenty of time for discussion and questions, so women and their families did not feel rushed and could be completely involved with the scan.
- Staff were committed to ensuring they achieved the best possible images for women. They explained about positioning and how this could optimise the chance of improving the image quality. We saw this occur with one woman. If women did not get the quality of image they were hoping for the service would book them in for an additional scan to ensure they received an image of good quality for a positive experience.

Are diagnostic imaging services responsive?

Good

We had not previously rated responsive. We rated responsive as **good.**

Service delivery to meet the needs of local people

- **The service planned and provided services in a way that met the needs of local people.**
- The service enabled women and their families to have access to ultrasound services throughout their pregnancy without the requirement of a referral. This meant they were able to continue to see the progress of their baby at any time during their pregnancy. The scans provided were designed to fit around a women's routine scans as part of the NHS care.
- The environment was responsive to the needs of the service. The waiting room was spacious with

comfortable seating for women and their families. Within the scan room there was seating to accommodate up to six family members or friends. The image from the ultrasound machine was projected both onto the wall and onto a television screen so everyone could see the images from where they were seated. Relaxing music was played to provide a soothing atmosphere. Children were also welcome to attend and there were toys available for them to play with. Baby changing facilities were also available at the location. Toilet facilities were near to the scan room and clearly identifiable for women.

- There were a range of packages and information available to women and their families to enable them to make informed choices regarding scans. These were displayed in the clinic, on the website and discussed in person. This enabled women to choose which scan was the most appropriate for them in their own time.
- Early pregnancy scans were popular at the clinic. This was because there was no provision locally under the NHS to receive these types of scans. Early pregnancy scans were available, so women could receive a scan at seven weeks gestation. This early scan package was designed for individuals who had undergone IVF, had recurrent miscarriages or a previous ectopic pregnancy, to enable early reassurance of viable pregnancies.
- The service also catered for women who chose to access obstetric ultrasound, in addition to routine antenatal ultrasound. The service also provided support to women who were receiving fertility treatment abroad, supporting consultants in their requests for measurements to be completed to identify optimum conditions for embryo transfer.
- Service provision included additional reassurance for women in their third trimester of pregnancy. 3D and 4D scans were provided or a basic well-being scan was also presented as an option.
- The service operated flexible opening hours to meet the needs of service users. Clinics were provided on week days, evenings and on a Saturday, making the service more accessible.
- Appointments were convenient, accessible and easy to make. Appointments could be made via telephone or via the service's online website. Women told us making an appointment had been easy and they had a choice of appointments. Invoices were sent as part of confirmation emails so that costs for the service were transparent.
- The cancellation process was made clear on booking an appointment. Women could change or cancel their appointments up to 48 hours prior to their appointment time. A refund was then received if any payment in the form of a deposit had been made.
- The service also offered non-invasive prenatal testing (NIPT). The prenatal test is a type of non-invasive prenatal screening. It looks at fragments of the baby's DNA in the woman's blood to provide accurate information about the likelihood for the most common chromosomal conditions from as early as 10 weeks gestation. There were clear pathways and referral routes used by the service when anomalies were identified.

Meeting people's individual needs

- **The service took account of women and their families individual needs** and was tailored to pregnant ladies. Appointments allowed women sufficient time to ask questions. The 30-minute appointments created a calm environment enabling women to discuss the scan results with the sonographer or enjoy their images in the privacy of the scan room. The long appointment times also meant that there was a low likelihood of women and their families having to share the waiting room with other women waiting for their appointment, making for a more personal experience.
- The scan room could accommodate six members of the women's family and friends to share the experience.
- The clinical admission policy set out set criteria for women who could attend the clinic, and at what time frame they could attend for the various scans provided by the service. Key information about what different ultrasound scans and what was involved were available on the service's website. It was clear about the type of scan that may be needed depending on the number of weeks the woman was pregnant. The website was set up as such that women had to read the information about the scan and the terms and conditions prior to booking.
- Women could access information about what they could expect at their appointment. This information was available on the services website.
- The scan couch could accommodate for bariatric women and there was wheelchair access to the waiting room and scan room via the back entrance.
- There was no access to an interpreting service, however, one of the sonographers spoke a number of languages

and was able to converse with the small number of Polish women and families which attended the service. There was also a small number of information leaflets in the waiting room which were also printed in Polish. The service had not encountered a need to use an interpreting service since the registered manager came into post in 2013.

- Information was sent to women prior to their non-invasive prenatal test (NIPT) to ensure they were fully informed of the test prior to attending the service. An email with links to independent websites offering information on NIPT was sent so that women and their families could gather together any questions that they may have before they arrived. This information was also available on the services website with additional links to further information. This ensured they were equipped with as much information as possible to ensure that they understood aspects of the test.
- Staff signposted women and their families to the support of a national charity if they were faced with a high probability screening test following NIPT testing. The charity was able to provide support and advice to parents facing potentially challenging situations.
- The scan room was private in case staff had to break any upsetting news to women and their family/friends. Women also had the option to exit via a different door when they had received bad news. This meant they avoided walking past other people attending the service if this occurred.
- The service provided women with information about how to access counsellors when pregnancy loss occurred. A Miscarriage Association card was also provided where women could access additional information to answer any questions that they did not ask during their appointment.
- Women were offered the opportunity to return to the service if the sonographer was unable to obtain good quality images. No one could predict the position of the baby at the time of the scan. This ensured the women had a positive experience and received a positive outcome to meet their expectations.

Access and flow

- **People could access the service when they needed it.**
- All women self-referred to the service. There was no waiting list and it was uncommon for the service to run with a delay. The registered manager told us of one occurrence in the last year where a woman and her family had waited 20 minutes for their appointment due to unforeseen circumstances. As a gesture, they were offered an additional scan on a subsequent day to ensure they had a positive experience.
- Appointments could be made in a number of ways. These could be booked using the services website using the online booking system. Bookings were also taken over the phone, providing opportunity to discuss their reason for booking and choosing a service which best suited their needs.
- Women were offered a choice of appointments. Diaries were opened three months in advance to give opportunity for potential service users to book a date that best suited them. Women told us there was plenty of choice. We saw how accommodating the service was when women wanted to change their appointment at short notice and as an example we saw an email from a woman who wanted to alter her appointment less than 48 hours before her scheduled appointment. The registered manager altered the appointment to a more convenient time requested by the woman.
- Sonographers gave results of the ultrasound to women and their families immediately after the scan. The report was typed when the images were being printed. The sonographer then explained the report to the women and their families to make sure they understood the information.
- Patients undergoing the NIPT screening had minimal time to wait for their results, between three and five days. The blood samples were sent via Royal Mail delivery to the laboratory within a day of the sample collection. The results were tracked by staff at the service who received an email to notify when the results were available. Staff gained consent to call women to advise of the results over the telephone. This meant that any concerning results could be referred to the NHS trust as soon as the patient was aware and gave consent for the referral. Women were offered a face to face appointment to receive their results.
- There had not been an event where appointments had been cancelled by the service. In the year prior to our inspection there had been 121 cancellations made by women. Of these 121, 42 cancelled their appointment to rearrange for another time, 31 clashed with NHS monitoring, 13 did not attend, 17 due to a pregnancy complication and 18 appointments were cancelled as they were no longer required.

Good

Diagnostic imaging

Learning from complaints and concerns

- **There was a system to manage complaints.**
- There was a complaint policy held by the service. The registered manager oversaw and managed complaints. The policy stated that complains would be dealt with within 72 hours by a telephone call from the registered manager.
- Staff were encouraged where possible to make immediate resolutions if patients complained, where this was possible, to ensure a positive experience for women and their families.
- There was information available for women and their families about how to make a complaint to the service. The website provided information about how to make a complaint. Women were provided with an information sheet on leaving the scan room encouraging them to raise any concerns before they left the clinic.
- There had been no formal complaints made to the service in over a year prior to our inspection, between September 2018 and December 2019.
- The service regularly received written compliments. We reviewed compliments received by women in the year prior to our inspection. Compliments included, 'a wonderful experience, lovely staff,' and had a 'warm welcome' and 'informative and helpful.'

Are diagnostic imaging services well-led?

Requires improvement

We had not previously rated well-led. We rated well led as **requires improvement.**

Leadership

- **Although we were not assured there was full oversight of the service, the registered manager was visible and approachable.**
- Leadership for the service was provided by the registered manager. They had been registered with CQC since 2013 and had seven years' experience of running the business.
- The registered manager was passionate about providing a positive experience for patients. This was demonstrated in the way they spoke about the service and how women were at the heart of the service. This was also demonstrated in how the service acted on feedback. This came from their professional and personal investment in the service.
- We were not fully assured that there was full oversight of the quality of the service. There was no programme of audit to identify where the service was performing well and areas for improvement.
- The registered manager was visible and approachable and present most days, taking on a hands-on approach to managing the service. This provided good oversight around the day to day running of the service.
- Staff told us the registered manager was very supportive, accessible and approachable. They valued that the registered manager worked alongside them at the clinic. They told us that if for some reason the registered manager was absent or on annual leave they could always get in contact to request advice or guidance by telephone.

Vision and strategy

- **The service had a vision for what it wanted to achieve.**
- The vision for the service was 'to create a welcoming, family friendly, but professional facility for expectant parents to enjoy an ultrasound session.' The current vision was to continue to provide a high-quality service for women. The registered manager also talked loosely about a longer-term vision to open another centre. However, no detail or timings had been thought about regarding this at the time of our inspection.
- The service was in the early stages of setting up a new private clinic which would be run by an obstetric consultant from a local NHS trust. The consultant had visited the clinic and was in talks with the registered manager as to how the service could be run and would work.

Culture

- **A positive culture was promoted that supported and valued staff.**
- Staff spoke positively about the culture of the service. The culture was centred around the needs of women and their families. Staff spoke passionately about their role and working at the service and were proud of the positive feedback the service received and how they could put women at the heart of the service in a luxurious environment making their experience special.

- Staff felt supported, respected and valued members of the service. The described the team as being 'supportive' and having 'good camaraderie.'
- Staff reported an open culture where they felt comfortable to raise concerns and approach the registered manager. They told us how supportive the registered manager was and how they were understanding and willing to support and provide cover if required.

Governance

- **Governance processes needed to be strengthened to enable the service to systematically improve service quality and safeguard high standards of care. There was no programme of audit to identify how the service was performing and to identify areas for improvement. Contemporaneous records were not always maintained around how the service was monitored and reviewed.**
- The registered manager was responsible for the governance of the service. There were some systems and processes to support the day to day running of the service, for example, the management of patient risk incidents and responding to patient complaints. However, some systems to ensure safety had not been set up. For example, there was no system to remind the registered manager of mandatory tasks such as equipment maintenance or electrical testing.
- Compliance with policies and procedures was not regularly checked as part of annual and/or monthly audit programme for the service. Therefore, there was a risk that there was not full oversight of the service and how it was performing, or to ensure the effectiveness of the service, for example, with consent, infection control or compliance with evidence-based guidance. This meant there was no process for the registered manager to identify areas which required improvement or areas in which the service was highly performing. Following the inspection, the registered manager told us they were going to review the percentage compliance against the cleaning schedules each week. However, we were told about good practice as the service carried out a peer review process to review the quality of the sonographers work.
- Contemporaneous records were not always maintained around monitoring the effectiveness of service delivery. There was no documented evidence that policies and procedures underpinning the service were regularly reviewed. Policies lacked a date, an author, review date or version control. Appraisals lacked documented evidence of any discussions which were held around current performance and future development.
- Staff meetings were held to keep staff updated. Minutes reviewed from staff meetings in June, August, October and November evidenced important information shared with staff at the meetings. However, agendas did not contain rolling topics for discussion to include complaints, feedback or incidents.
- Staff were clear about their roles and what they were accountable for. Staff knew to go directly to the registered manager if they needed support. There was an organisational structure chart which set out the roles and responsibilities for each member of staff working for the service. This provided additional clarity on roles and responsibilities.
- All staff had a completed DBS criminal record check to ensure they were of good character. A paper copy of the staff member, the date of their DBS check and their certificate number was held by the service.
- The service was not fully compliant with Schedule 3 of the Health and Social Care Act for safe recruitment. We reviewed records for five members of staff. Proof of their identity had been obtained for their DBS. However, copies of the proof of identify documents with a photo and address had not been retained. All of the files contained application forms, documented evidence of relevant qualifications, employment history and two written references from previous employers. All staff had a signed terms and conditions document, which provided information about their role, responsibilities and terms and conditions of their employment. There was a staff training and selection policy, which included a recruitment checklist. We did not see this checklist had been completed for any staff recruitment in the staff files and the checklist did not cover all aspects of Schedule 3 associated with recruitment procedures. Following the inspection, we were told proof of identify documents had been taken and stored in each staff file.
- The service held medical malpractice insurance and employer and public liability insurance which were in date.
- The service had introduced an electronic portal six months ago with a view to storing information about the service such as incidents, complaints, appraisals and mandatory training. At the time of our inspection, the

registered manager was still learning to use the system. One staff appraisal from 2019 had been added along with mandatory training data for all staff. Work was ongoing for the registered manager to learn to use the systems and transfer information.

Managing risks, issues and performance

- **The service had systems to identify risks and controls to reduce them, and cope with both the expected and unexpected.**
- The risks to the service were assessed using a risk assessment proforma. A health and safety risk assessment for the service had been carried out in April 2019, two in October 2019 and a further one in February 2020. The assessment included associated risks with the service. These included slips and trips, scalding from hot water and pregnant workers lifting items whilst at work. The assessment identified the controls which were already ongoing to mitigate the risk. The assessment also identified a responsible person who was managing each risk.
- A bespoke fire risk assessment for the service had been completed by an external company. The assessment identified potential fire risks, rated the individual risk and identified the actions required to manage the risk. The risk assessment had been completed in April 2019 and was due to be reviewed in 12 months.
- There was a business continuity policy to ensure continuity of the service or the appropriate course of action in the event of an incident occurring such as flooding, machine breakdown or staff unavailability. The policy covered each hazard which could pose a risk to the business and identified the mitigation and action required to manage each issue.

Managing information

- **The service collected, analysed, managed and used information well to support all its activities, using secure electronic systems with security safeguards.**
- Staff had access to Early Life Ultrasound Centre policies and processes covering relevant areas. We saw evidence that staff were required to sign to confirm they had read the policies on a yearly basis.
- The service was compliant with the General Data Protection Regulation (GDPR) 2018. The privacy policy set out the GDPR requirement and consent was obtained from women to store their records and that it was held for no longer than is deemed necessary.
- Women were made aware of the terms and conditions of the services through the website. These were also documented on the consent form signed by women.
- The records policy detailed the practice in relation to the retention of personal data and disposal of information. Retention periods were clearly set out in the policy and followed by the service. Further information in the policy provided information for staff to follow if data protection had been breached and what staff must do in the event of this occurring.
- The service was registered with the Information Commissioner's Office (ICO), in line with The Data Protection (Changes and Information) Regulations (2018). The services registration needed renewing in February 2020. The ICO is the UK's independent authority set up to uphold information rights.

Engagement

- **The service engaged well with women and their families and used feedback to improve the service.**
- Social media was a platform used to engage with people. It also enabled the monitoring of feedback and reviews.
- The service no longer sent routine emails to women following their appointment to request feedback. This system ceased in June 2019 as it was identified that minimal feedback was given in this way. The service had changed the process to provide women with information on leaving the scanning room as to how to provide feedback. This could be done on a number of social media platforms. Alternatively, women could provide feedback more privately to the service's email address, should they not wish to provide public feedback for personal reasons.
- There was evidence that change was delivered as a result of feedback. The service had received poor feedback about a gender scan. Following the feedback, communication was improved to women and their families before the scan to ensure they had a more realistic expectation at the start of the scan.
- Negative feedback was followed up directly to identify areas for service improvements. We saw an example of an email sent to a woman following negative feedback provided via a social media website. The woman was encouraged to get in contact with the service, so they could discuss the issues further and look to where they could learn and improve.

Good

Diagnostic imaging

- Staff felt able to share their opinions and provide feedback at staff meetings or more regularly on a day to day basis with the registered manager. Staff provided us with an example of changes made to implement a more formal cleaning schedule so that the load was shared equally among the staff.

Learning, continuous improvement and innovation

- **The service was committed to improving services by learning from when things went well or wrong.**
- All staff were committed to offering the best available scan images. We were given examples when women reattended the service because high quality images could not be obtained during the initial scan.
- The service used feedback to make improvements to ensure women had a positive experience. We saw examples of how the service had acted on negative feedback and the changes which the service had made as a result.

Outstanding practice and areas for improvement

Outstanding practice

- The service responded well to identified risks to patients. The service recognised the need for an urgent transfer in a timely way, ensuring the safety of the patient.

Areas for improvement

Action the provider MUST take to improve

- Ensure compliance with Schedule 3 in accordance with the Health and Social Care Act.
- Ensure there are audit processes established to improve the quality and safety of the service being provided.
- Ensure contemporaneous records are maintained to demonstrate how decisions are made using information from the service to improve governance and ensure oversight. For example, around policies and appraisals lacked documented evidence of any discussions which were held around current performance and future development.

Action the provider SHOULD take to improve

- Update the safeguarding policy to include information about female genital mutilation, child sexual exploitation and the telephone number to use when contact the local authority with safeguarding referrals.
- Encourage staff to remain bare below the elbow as set out in the services infection control policy.
- Label sharps bins to identify when they were first used.
- Develop a formal standardised induction checklist for staff starting employment at the service.
- Review the duty of candour and its principles to ensure a thorough understanding.
- Review the appraisal process to make sure there is evidence of discussions about current performance and future development.

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 17 HSCA (RA) Regulations 2014 Good governance Ensure there are clear and regular audit processes to monitor and improve the quality, effectiveness and safety of the service being provided. Ensure contemporaneous records are maintained to demonstrate how decisions are made using information from the service to improve governance and oversight. For example, around policies, documented evidence of discussions held during staff appraisals and assurance of compliance with policies and procedures. Regulation 17(1)

Regulated activity	Regulation
Diagnostic and screening procedures	Regulation 19 HSCA (RA) Regulations 2014 Fit and proper persons employed The registered manager must ensure compliance with Schedule three of the Health and Social Care Act for safe recruitment Regulation 19(2)