

Verulam Clinic





Quality Report

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

Ratings

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

Summary of findings

Letter from the Chief Inspector of Hospitals

Verulam Clinic is operated by Verulam Clinic Limited. The service provides diagnostic pregnancy and fertility imaging services (ultrasound scans) to self-funded women in St Albans and the surrounding areas.

The service also offers additional services, which are not included in their regulated activity. This includes complementary health treatments and small group classes to couples, mothers, and babies.

We inspected this service using our comprehensive inspection methodology. We carried out an unannounced inspection on 5 December 2018.

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.

Services we rate

We have not previously rated this service. At this inspection in December 2018, we rated the service as **good** overall.

We found areas of good practice:

- Staff were caring, kind and engaged well with women and their families.
- Services were planned in a way that met the needs of women and the local community. Women were offered a choice of appointments.
- Managers promoted a positive culture that supported and valued staff. Staff confirmed they felt respected and valued.
- The service used current evidence-based guidance and good practice standards to inform the delivery of care and treatment. Staff demonstrated a good understanding of the national legislation that affected their practice.
- Verulam Clinic had a clear vision and strategy for what they wanted to achieve, with quality and sustainability as the top priorities.

However, we found the following areas of practice that the service needed to improve:

- Staff did not receive mandatory training in key skills after their initial induction to the service. There was no oversight on what training the sonographers had completed at their substantive employer.
- While staff understood the need to protect people from abuse, they had not all completed safeguarding training at the required level to ensure they had the appropriate knowledge to do so. However, this was rectified after our inspection.
- Verulam Clinic did not have full oversight of the competencies, skills and capabilities of staff working for their service. There was no formal staff appraisal system in place at the time of our inspection. However, this was rectified after our inspection.
- We were not assured that the service always kept up-to-date with important national and statutory legislation.
- Informed consent was not appropriately gained from women who did not have English as their first language. However, this was rectified after our inspection.

Summary of findings

- While the service generally had effective arrangements in place for identifying and recording risks, there was little evidence that these risks and their mitigating actions were discussed with the wider team.

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 one requirement notice that affected Verulam Clinic. Details are at the end of the report.

Amanda Stanford

Deputy Chief Inspector of Hospitals (Central)

Summary of findings

Our judgements about each of the main services

Service

Diagnostic imaging

Rating

Summary of each main service

Good



The provision of ultrasound scanning services, which is classified under the diagnostic core service, was the only core service provided at Verulam Clinic. We rated the service as good overall because there were processes in place for the escalation of unexpected findings during ultrasound scans. Feedback was extremely positive. Appointments were scheduled to meet the needs of women who required their services, and the clinic manager had the appropriate skills and experience to manage the business.

However, there was not a renewable mandatory training programme or appraisal system in place for staff at the time of our inspection. Not all staff had completed safeguarding training at the required level; however, this was rectified after our inspection. Informed consent was not appropriately gained from women who did not have English as their first language; however, this was also rectified after our inspection.

Summary of findings

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Good 

Verulam Clinic

Services we looked at

Diagnostic imaging.

Summary of this inspection

Background to Verulam Clinic

Verulam Clinic is an independent private diagnostic service based in St. Albans, Hertfordshire, and is operated by Verulam Clinic Limited. Verulam Clinic was established eight years ago. It provides diagnostic pregnancy and fertility imaging services (ultrasound scans) to self-funded women, aged 18 years and above, in St Albans and the surrounding areas. All ultrasound scans performed at Verulam Clinic are in addition to those provided through the NHS.

Verulam Clinic was initially established to offer nuchal translucency ultrasound screening, which was not available through the NHS at the time. Since this, the service evolved and now offers:

- Early pregnancy scans.
- Fertility scans.
- Growth and reassurance scans.

- Gynaecology scans.

Verulam Clinic no longer offers nuchal translucency scans as these are now routinely offered on the NHS.

The service has had a registered manager in post since registering with the CQC in 2011. Verulam Clinic had been previously inspected in November 2013 and was compliant in three of the five areas inspected. They were not compliant in complaints or requirements relating to workers. A follow-up inspection was undertaken in July 2014 and Verulam Clinic now met the standards for complaints but remained non-compliant with the requirements relating to workers.

Verulam Clinic is registered with the CQC to undertake the regulated activity of diagnostic and screening procedures.

Our inspection team

The inspection team was comprised of a CQC lead inspector and a CQC assistant inspector. The inspection team was overseen by Phil Terry, Inspection Manager, and Bernadette Hanney, Head of Hospital Inspection.

Information about Verulam Clinic

The service is radiographer-led and provides diagnostic imaging services (ultrasound scans) to self-funded women within St Albans and the surrounding areas.

The service offers diagnostic pregnancy and fertility ultrasound scans, including:

- Viability and early pregnancy and assessment scans from six weeks' gestation.
- Sexing scans from 16 weeks' gestation.
- Growth and reassurance scans.
- 4D baby scans performed from 24 to 34 weeks' gestation.

- Scans during fertility treatment, including ovulation scans.

They do not offer nuchal translucency scans or the 20-week anomaly scans. This is because these diagnostic tests are offered as part of the current NHS pregnancy pathway. They also do not offer non-invasive prenatal tests (NIPT).

Verulam Clinic also offers additional services, which are not included in their regulated activity. This includes complementary health treatments, such as reflexology, occupational therapy, hypnotherapy, acupuncture, and counselling. They also offer small group classes to couples, mothers, and babies, such as hypnobirthing, pregnancy yoga and baby massage.

Summary of this inspection

Approximately 95% of women accessing the service self-refer to the clinic. The service does receive a small number of referrals from GPs, however, the women are still seen as private (paying) patients.

The service runs approximately five clinics per week and sees between 30 to 40 women. Standard operational hours are Monday morning, Wednesday lunchtime, Thursday evening, and Friday and Saturday morning.

At the time of our inspection, Verulam Clinic employed four part-time receptionists and three sonographers, who had previous obstetrics and gynaecology experience. There were also therapists who worked out of Verulam Clinic on a self-employed basis. These included registered healthcare professionals, such as osteopaths, physiotherapists, and clinical psychologists.

During our inspection, we visited the registered location in St Albans. We spoke with four staff members, including the clinic manager, receptionists, and a therapist. We also observed one ultrasound scan, spoke with one woman and her partner, and reviewed four 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.

Activity:

- Verulam Clinic performed a total of 1,809 ultrasound scans from December 2017 to November 2018. A breakdown of the type of scan can be seen below:
- 145 (8%) fertility scans.
- 1,013 (56%) early pregnancy scans.
- 222 (12.3%) gender scans.
- 225 (12.4%) growth scans.

- 174 (9.6%) 4D scans.
- 30 (0.06%) gynaecology scans.
- All women were self-funded.
- For the reporting period of December 2017 to November 2018, Verulam Clinic did not cancel any patient appointments for non-clinical reasons.
- For the reporting period of December 2017 to November 2018, no procedures were delayed due to non-clinical reasons.

Track record on safety:

- The service reported zero never events from December 2017 to November 2018.
- The service had recorded zero incidents from December 2017 to November 2018.
- The service reported zero serious injuries from December 2017 to November 2018.
- The service received one complaint from December 2017 to November 2018, which was not upheld.
- Verulam Clinic received eight written compliments September 2017 to September 2018.
- Verulam Clinic reported zero incidents of health associated MRSA, Methicillin-sensitive staphylococcus aureus (MSSA), Clostridium difficile (C. diff), and Escherichia Coli (E-Coli).

Services provided under service level agreement:

- Clinical and non-clinical waste removal.
- Weekly clinic cleaning.
- Ultrasound maintenance and repair.

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

Notes

We do not rate effective.

Diagnostic imaging

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

Are diagnostic imaging services safe?

Good 

We have not previously rated this service. At this inspection, we rated safe as **good**.

Mandatory training

- **Staff did not receive mandatory training in key skills after their initial induction to the service. There was no oversight on what training the sonographers had completed at their substantive employer.**
- At the time of our inspection, there was not a renewable mandatory training programme in place. When staff first joined the service, they were required to complete mandatory training courses, including health and safety, and fire and evacuation. However, no refresher training courses were provided. This meant that some staff had not completed any mandatory training since joining the service almost 10 years ago. We raised this as a concern to the clinic manager during our inspection, who told us they would implement a rolling mandatory training programme. Following our inspection, we received confirmation that all refresher training would be completed by the end of January 2019. However, there was no indication regarding the future frequency of the two mandatory training programmes (fire and evacuation, and health and safety).
- Two sonographers, who worked part-time for the service, completed their mandatory training at their substantive NHS employer. However, Verulam Clinic did not have oversight on what training these

individuals had completed or when. We also raised this as a concern during our inspection and were told that the sonographers' training matrix would be requested and stored in their staff personnel files.

- While the clinic manager believed the sonographers had received training on information governance, basic life support, infection prevention and control, consent and mental capacity at their substantive employer, there was no evidence to support this. Similarly, we were not assured that the clinic manager had completed all the relevant training.

Safeguarding

- **While staff understood the need to protect people from abuse, they had not all completed safeguarding training at the required level to ensure they had the appropriate knowledge to do so. However, this was rectified after our inspection.**
- At the time of our inspection, the clinic manager had completed level two adults safeguarding training and the clerical manager had completed level one adults safeguarding training. However, neither manager had completed safeguarding children's training. It was also not clear what level of safeguarding training (adults or children) the receptionists or other sonographers had completed.
- Although Verulam Clinic did not provide ultrasound services to adolescents under the age of 18 years, children frequently attended ultrasound scan appointments with their mothers. Verulam Clinic also provided new-born services outside of their regulated activity, including baby massage. Therefore, the service's current safeguarding training did not meet

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national guidance laid out in the Intercollegiate Document, 'Safeguarding children and young people: roles and competences for health care staff', (March 2014).

- Although staff had not completed the appropriate safeguarding training, they could confidently tell us how they would identify a safeguarding issue and what action they would take.
- Following our inspection, the clinic manager reviewed the safeguarding training requirements. We were provided with evidence which showed that all the receptionists had now completed level one adults and children safeguarding training, and the clinic manager had completed level three children safeguarding training. Similarly, the clinic manager confirmed that the sonographers had completed both level two adults and children safeguarding training at their substantive NHS employer. This meant that safeguarding training was now in accordance with national legislation.
- From December 2017 to November 2018, the service had not made any safeguarding referrals.
- While the service had up-to-date adults and children safeguarding policies in place, which referenced the contact details of the local safeguarding boards, it did not provide staff with clear guidance on how to identify or report female genital mutilation (FGM) or child sexual exploitation (CSE). Staff told us that if they were concerned about any woman or child, they would refer to the local safeguarding team. After the inspection, the clinic manager updated both safeguarding policies to include information on FGM and CSE.

Cleanliness, infection control and hygiene

- **The service controlled infection risk well. Staff kept themselves, the equipment, and the premises clean.** The clinic room, reception and waiting room were visibly clean and clutter free on the day of our inspection.
- Verulam Clinic had infection prevention and control (IPC) policies and procedures in place, which provided staff with guidance on appropriate IPC practice.
- There was a dedicated, external cleaner who was responsible for the cleaning of the clinic room, waiting

room, bathrooms, and reception area. Cleaning was recorded on a weekly check sheet, which was reviewed by the clinic manager. We reviewed the cleaning checklists from 21 September to 31 November 2018 and saw weekly cleaning had been completed.

- There were carpets on the floors in some of the clinical areas, which is not in line with IPC best practice. However, the clinic manager was aware of the risk this presented and had acted to mitigate any risk until modification to the environments could be made. This included six-monthly deep cleaning of the carpets, or sooner if required. At the time of our inspection, no formal risk assessment had been completed. However, after our inspection, the clinic manager completed a risk assessment which confirmed the mitigating actions already in place.
- The sonographers followed the manufacturer's and IPC guidance for routine disinfection of equipment. Staff decontaminated the ultrasound equipment with disinfectant wipes between each woman and at the end of each day. We observed staff cleaning equipment and machines during our inspection.
- All women who underwent a transvaginal ultrasound scan were asked if they had any allergies to latex. The service had both latex and non-latex covers for the transvaginal ultrasound probe, and they would select the cover according to the response from the woman.
- Staff used paper towel to cover the examination couch during the scanning procedure. We observed staff changing the towel at the end of the woman's appointment.
- A supply of personal protective equipment (PPE) was available and accessible to all staff. Staff used the PPE appropriately when interacting with women, and all had their 'arms bare below the elbows' in clinical areas.
- Staff washed their hands using the correct hand hygiene techniques before, during and after patient contact. Hand washing basins and sanitiser gels were available in the clinic room and bathrooms.
- Hand hygiene audits were not undertaken to measure staff compliance with the World Health Organisation's (WHO) 'Five Moments for Hand Hygiene'. These

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guidelines are for all staff working in healthcare environments and define the key moments when staff should perform hand hygiene to reduce the risk of cross contamination between patients. We raised this as a concern during our inspection. We were told that it would be difficult to complete an accurate audit due to the size of the service and the number of staff employed.

- The clinic manager recognised that transvaginal scans increased the risk of patient infection. As a result, they had implemented a cleaning protocol for these scans, which included an IPC checklist for sonographers to complete. The checklists included a prompt regarding hand hygiene. We reviewed the checklists from 2 October to 3 December 2018 and found they had been completed appropriately.
- There had been no instances of healthcare acquired infections from December 2017 to November 2018.

Environment and equipment

- **The service had suitable premises and equipment and looked after them well.** Verulam Clinic recently purchased a new high-tech ultrasound system, which provided women with high-quality images.
- An external company completed the servicing of the ultrasound machine. The service record for the machine confirmed it had been serviced annually, the last completed in October 2018. Where faults arose outside of the planned services, staff called out engineers to assess and perform repairs.
- The environment in which the scans were performed were spacious and well arranged by the service. Staff turned the lights off and pulled the curtains when undertaking a scan to darken the room, which meant scans could be observed clearly. This also promoted the privacy and dignity of women. Similarly, a sign reminding staff to knock before entering the clinic room had been placed on the outside of the door.
- The waiting room for the service had adequate seating available and a patient toilet was accessible close to the clinic and waiting room.

- There was a separate entrance for wheelchair users, which was accessed through the back of Verulam Clinic. The clinic room also contained an adjustable couch, which staff used to support women with limited mobility.
- Waste was handled and disposed of in a way that kept people safe. Staff used the correct system to handle and sort clinical and non-clinical waste, and there was a service level agreement in place for its removal.
- At the time of our inspection, the service did not have resuscitation or first-aid equipment for staff to use in an emergency. The clinic manager had sought advice from a health and safety consultancy firm, who informed them that they only required adhesive plasters. After our inspection, the clinic manager purchased a 'British standard workplace first aid kit', which included assorted dressings, foil blanket, mouth-to-mouth resuscitation device with valve, antiseptic wipes, and a first aid guidance leaflet.

Assessing and responding to patient risk

- **The service had appropriate arrangements in place to manage risks to women, their babies and families.**
- At the time of our inspection, there was no evidence that staff had undertaken first aid or basic life support training to support women, staff or visitors who may feel unwell or deteriorate during their visit to the Verulam Clinic. However, after our inspection the clinic manager completed 'emergency first aid at work' training.
- There was clear guidance for staff to follow if a woman or visitor suddenly became unwell whilst attending the clinic. If staff had concerns about a woman's condition during their ultrasound scan, they stopped the scan and telephoned 999 for emergency support. From December 2017 to November 2018, the service had not reported any incidents that related to staff having to call for an ambulance or a woman deteriorating during their appointment.
- Whilst the service did not formally use the 'Paused and Checked' checklist devised by the British Medical

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Ultrasound Society and Society of Radiographers, the sonographer completed the checks subconsciously during their appointments. For example, we observed the sonographer:

- Confirmed whether the scan was justified.
- Confirmed the woman's identity.
- Gained the woman's consent.
- Provided clear information and instructions to all involved, including the potential limitations of the ultrasound scan.
- Informed the woman about the results.
- Scan reports were completed immediately after the scan had taken place, which we observed during our inspection.
- There were clear procedures in place to guide staff on what actions to take if any suspicious findings were found on the ultrasound scan. If any concerns were detected, the sonographer contacted the woman's GP, consultant obstetrician or midwife, with consent. If the woman did not consent for the information to be passed on, the sonographer encouraged the woman to contact an appropriate healthcare professional as soon as possible. Where concerns were identified, the sonographer followed this up after the appointment to ensure appropriate action had been taken.
- Staff provided us with examples of when they had used the escalation process after unexpected findings had been identified on a scan. For example, following a routine scan, a sonographer identified an issue with a baby's organ. The sonographer encouraged the woman to speak with her consultant obstetrician urgently. As a result, the woman was referred to a specialist hospital during her pregnancy and the baby was treated immediately after birth.
- During their appointments, staff advised women about the importance of still attending their NHS scans and appointments. The sonographers made sure women understood that the ultrasound scans they performed were in addition to the routine care they received as part of their maternity pathway. This advice was also included on the service's website.

- The service accepted women who were physically well and could transfer themselves to a couch with little support. The service did not offer emergency tests or treatment.

Staffing

- **The service had enough staff with the right qualifications and experience to provide the right care and treatment.**
- There were four part-time receptionists, who made up 1.5 full time equivalent, including the clerical manager. The receptionists were responsible for managing enquiries and appointment bookings.
- The service employed three sonographers on zero-hour contracts, who were all radiographers and had previous obstetrics and gynaecology experience. This included the clinic manager, who was responsible for producing staff rotas and managerial processes.
- There were also qualified therapists, who worked out of Verulam Clinic on a self-employed basis. These included registered healthcare professionals, such as osteopaths, physiotherapists, and clinical psychologists.
- All staff we spoke with felt that staffing was managed appropriately. At all times, there were at least two staff in the clinic; this included a receptionist and a sonographer. No staff members were required to work as a 'lone worker'. Where staffing levels fell below this agreed threshold, all clinic appointments would be rearranged.
- Verulam Clinic did not use bank or agency staff. In the event of a staff member going off sick, the receptionists and sonographers would cross-cover between themselves to help prevent clinic cancellations.
- From July to September 2018, the service reported an average sickness rate of 0%.
- Information provided by the service indicated that no staff members had left the service within the last 12 months. However, two staff members were due to leave the service in December 2018. This included the

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clerical manager and a sonographer, who had both worked at the service for almost 10 years. At the time of our inspection, the clerical position was being advertised.

Records

- **Staff kept detailed records of women's care and treatment. Records were clear, up-to-date, and easily available to staff providing care.**
- Staff generally stored and updated individual patient care records in a way that protected women from avoidable harm and maintained their confidentiality. However, we found four records stored in an unlocked draw in the kitchen of Verulam Clinic. The records included personal details, ultrasound scan reports and scan images. We raised this as a concern to the clinic manager who removed the records immediately and stored them in a locked cupboard in the clinic office.
- The sonographer undertaking the ultrasound scan completed the scan report during the woman's appointment. The report was saved onto a USB stick, which was given to the woman to take away with her. Where appropriate, and with consent, the sonographer would also send a paper or electronic copy of the scan report to the woman's GP or another relevant healthcare professional the same day. The service also stored paper-copies of scan reports and scan images, in case they needed to refer to the documents in future.
- Scan reports could also be sent electronically to women and other healthcare services by encrypted email.
- We reviewed four records during the inspection. Staff recorded all the specified information in a clear and accurate way. This included their estimated due date, the type of ultrasound scan performed, the findings and recommendations.

Medicines

- The service did not use any controlled drugs or medicines for any of their procedures.

Incidents

- **Verulam Clinic had processes in place for staff to raise concerns and report incidents. However, staff had not reported any incidents within the last 12 months.**
- The service used a paper-based reporting system, and incident forms were available in the clinic for staff to access, if required. Completed forms were given to the clinic manager, who was responsible for conducting investigations into all incidents. The process for incident reporting and investigating was outlined in the service's incident reporting policy.
- Although staff had not reported any incidents from December 2017 to November 2018, they could describe the process for reporting incidents and provided examples of when they would do this, such as information governance breaches or patient accidents.
- Verulam Clinic did not have any never events in the 12 months prior to our inspection. A never event is a serious incident that is wholly preventable as guidance, or safety recommendations providing strong systemic protective barriers, are available at a national level, and should have been implemented by all providers. The event has the potential to cause serious patient harm or death, has occurred in the past and is easily recognisable and clearly defined.
- In accordance with the Serious Incident Framework 2015, the service did not report any serious incidents in the 12 months prior to our inspection.
- Regulation 20 of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014 is a regulation which was introduced in November 2014. This regulation requires the organisation to be open and transparent with a patient when things go wrong in relation to their care and the patient suffers harm or could suffer harm, which falls into defined thresholds. The duty of candour regulation only applies to incidents where severe or moderate harm to a patient has occurred.
- Staff understood the duty of candour and the need for being open and honest with women and their families if errors occurred. The clinic manager could explain

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the process they would undertake if they needed to implement the duty of candour following an incident, which met the requirements. However, at the time of our inspection, they had not needed to do this.

The clinic manager was aware of the requirements for reporting incidents to the CQC using the statutory notification route if this met the criteria, under Regulation 18 of the Care Quality Commission (Registration) Regulations 2009.

Are diagnostic imaging services effective?

We do not rate effective.

Evidence-based care and treatment

- **The service used current evidence-based guidance and good practice standards to inform the delivery of care and treatment.** Staff demonstrated a good understanding of national legislation that affected their practice.
- Local policies and protocols were in line with current legislation and national evidence-based guidance from professional organisations, such as the National Institute for Health and Care Excellence (NICE) and the Royal College of Obstetricians and Gynaecologists (RCOG). An example of RCOG guidance that the service followed was 'The management of early pregnancy loss', green top guideline No.25.
- All policies and protocols contained a next renewal date, which ensured they were reviewed in a timely manner.
- Staff were aware of how to access policies, which were stored electronically on an internal computer drive. Paper-copies were also accessible to staff.
- Prior to our inspection, the service had recently initiated an annual clinical audit programme. Clinical audits were completed at least three times a year and audited local practice against national guidance.
- Staff ensured women understood that the ultrasound scans performed at Verulam Clinic were in addition to those provided as part of their NHS pregnancy pathway and were not designed to replace any NHS care.

- We observed a sonographer providing clear information to a woman about her ultrasound scan, including the potential limitations of the scan.
- 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.

Nutrition and hydration

- To improve the quality of the ultrasound image, women were asked to drink two glasses of water one hour prior to their appointment time. Women were provided with this information when they contacted the clinic to book their appointment. It was also included on their confirmation booking email.
- Due to the nature of the clinic, food and drink was not routinely offered to women. However, there was a drinking water dispenser in the waiting room, which was accessible to women and visitors.

Pain relief

- Staff asked women if they were uncomfortable during their ultrasound scans, however, no formal pain level monitoring was undertaken as the procedures were pain free.

Patient outcomes

- **Staff monitored the effectiveness of care and treatment and used the findings to improve their practice.** The service monitored patient outcomes through their activity, annual patient satisfaction survey and clinical audits.
- The service completed clinical audits at least three times a year. The audits reviewed the effectiveness of care and treatment provided against national guidance and legislation. For example, in September 2018, the service audited all growth scans completed between June and August 2018. Each scan measurement was graded as 'good', 'acceptable' or 'poor' based on the fetal anomaly screening programme (FASP) grading system. Out of the 33 scan measurements reviewed, 48% were graded as 'good'

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and 42% were graded as 'acceptable'. No measurements were graded as 'poor'. However, three measurements (9%) were not able to be graded due to the limited availability of scan images.

- Audit results indicated that the sonographers did not always print enough scan images to evidence the conclusions made in their scan reports. The audit findings were sent to the sonographers and they were reminded about the importance of completing and printing all fetal measurements taken. The service planned to re-audit their performance in 2019.
- Service activity, clinical audit results and patient feedback were regularly discussed during the monthly team meetings. e

Competent staff

- **Staff had the skills, knowledge and experience to deliver effective care and treatment to women. However, managers did not formally appraise staff's work performance.**
- At our last inspection in July 2014, we identified concerns with staff personnel files. We found that not all files contained evidence of an interview or references. At this inspection in December 2018, improvements had been made. The personnel file for the most recently employed staff member contained all the necessary documents, including two satisfactory references and evidence of an interview. The clinic manager demonstrated an awareness of the previous lack of recruitment process and provided assurance that there was now a robust process in place.
- As part of our inspection, we reviewed four staff personnel files. We found they all contained evidence of a recruitment and selection interview, employment history, identification, employment contract, and disclosure and barring service (DBS) checks. DBS checks help employers make safer recruitment decisions and prevent unsuitable people from working with vulnerable groups.
- All three sonographers were registered with the Health and Care Professionals Council (HCPC) and the Society

of Radiographers, and there was evidence of their professional registration in their personnel files. The sonographers all had previous obstetrics and gynaecology experience within an NHS acute trust.

- Although the therapists worked out of Verulam Clinic on a self-employed basis, the clinic manager ensured they were of good character and competent for their role. Each year, the clinic manager reviewed and took copies of their professional registration, professional indemnity insurance, identification, and their DBS check. However, Verulam Clinic did not have oversight on what mandatory training the sonographers had completed at their substantive NHS employer.
- Each staff member completed a local induction, which included mandatory and role-specific training. Newly employed sonographers worked closely with the clinic manager, which enabled the manager to assess competence and address any issues with the individual before they worked alone.
- There was no formal appraisal system in place for staff. This meant we could not be assured that staffs' learning needs would be identified in a timely manner. Appraisals also provide evidence that individuals still hold the necessary skills and competencies to undertake their role safely and effectively.
- While staff confirmed that they would welcome development opportunities, they felt a formal appraisal system was not needed. This was because they felt comfortable to raise their training needs and concerns directly with the clinic manager. However, the clinic manager planned to commence staff appraisals in January 2019. This was corroborated by the November 2018 staff meeting minutes where the topic of appraisals had been discussed with staff. After our inspection, we were provided with assurance that the clinic manager had commenced staff appraisals.
- The clinic manager used an external human resources consultancy firm to support them to manage poor staff performance, if required. They also sought advice from the Federation of Small Businesses.

Multidisciplinary working

- **Staff of different disciplines worked together as a team to benefit women and their families.**

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- Staff employed by Verulam Clinic worked closely with other healthcare professionals, such as osteopaths, physiotherapists, and clinical psychologists, who worked at the clinic on self-employed basis. All staff reported excellent working relationships with each other and told us they felt “like a family”. Examples were given where the therapists were invited to Verulam Clinic social events, and the clinic manager promoted the therapy services through their social media pages and website.
- During our inspection of Verulam Clinic, we observed positive examples of the sonographer and receptionists working well together. Their professional working relationship promoted a relaxed environment for women and helped to put women and their families at ease.
- Although there were no formal meetings between the clinic manager and the various therapy services, they had regular informal catch-up sessions, and the therapists were consulted about changes to service provision. The clinic manager had also set-up a closed Facebook page which enabled all staff working at Verulam Clinic to share good practice and topics of interest.
- Staff told us if they identified any findings, which required escalation to another health provider, staff would immediately communicate their findings with the woman’s GP, midwife, or other relevant healthcare professional, with their consent.

Seven-day services

- **As Verulam Clinic was not an acute service and did not offer emergency tests or treatment, it did not operate seven days a week.**
- Clinics were held on a Monday morning; Wednesday lunchtime; Thursday evening; Friday morning, and Saturday morning.
- If women were unable to attend one of the arranged clinics, the clinic manager often saw the women outside of these times.

Consent and Mental Capacity Act

- **While staff were aware of the importance for gaining consent from women before undertaking any ultrasound scan, informed consent was not appropriately gained from women who did not have English as their first language.**
- Staff told us that implied consent was assumed when women booked their appointment, paid the fee, and entered the clinic room. However, women’s verbal consent was also sought prior to the sonographer commencing the ultrasound scan.
- Women were provided with information prior to their appointments and were given opportunities to ask questions when they arrived. This ensured the verbal consent was informed. Similarly, sonographers discussed the potential risks to the unborn child from additional use of ultrasound with the women. This enabled the woman to make an informed decision on whether to proceed with the scan.
- Women’s relatives or friends were sometimes used as interpreters by staff when English was not the woman’s first language. We were concerned that these women may not fully understand what the scan involved or their scan results, and as a result, informed consent could not be appropriately sought by the sonographers. We raised this as a concern to the clinic manager, who took immediate action. Following our inspection, staff could access telephone translation services.
- Staff gave women the option of withdrawing their consent and stopping the scan at any time. The woman we spoke with confirmed their consent had been obtained throughout the scanning process.
- Staff obtained women’s consent to share information and scan results with their GP, midwife, or other healthcare professional. In these situations, the sonographers clearly explained why this was necessary to the women.
- While staff understood the principle of assessing mental capacity and best interest decisions, they had not received formal Mental Capacity Act (2005) training. We raised this as a concern with the clinic manager who told us that this training was not relevant to their service as women self-referred for their appointments.

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Are diagnostic imaging services caring?

Good 

We have not previously rated this service. At this inspection, we rated caring as **good**.

Compassionate care

- **Staff cared for women with compassion. Feedback from women and their families confirmed that staff treated them well and with kindness.**
- During our inspection, we observed one patient being scanned. The sonographer was observed to be very reassuring and interacted with the woman and their relative in a professional, respectful, and supportive way. The woman told us that they had frequent scans at Verulam Clinic because she felt very anxious during her pregnancy. They reported that the staff were always caring and very reassuring.
- Staff protected women's privacy and dignity; the women were kept covered as far as possible, there were curtains over the clinic room window and a sign on the clinic room door to remind people to knock before entering. There was also a curtain that could be pulled across the door to obscure the view of anyone entering the clinic room.
- The reception was located away from the waiting area, and so women could speak to receptionists without being overheard. However; whilst in the waiting room, we could hear small parts of conversations from the clinic room. Following the inspection, we were told that this was being addressed by reminding staff to keep voices low, using the curtain to muffle sounds and the consideration of playing music in the waiting room.
- The service offered the option of a chaperone, which would be one of the female reception staff. There was a notice in the waiting room reminding women to ask if they required this.

- We looked at the results from the latest patient feedback survey, which took place in September 2018. There were 24 responses, with no negative feedback and all reported that they would definitely recommend the service.
- We read some feedback from women, that had been sent by letter or email. All the feedback was extremely positive, and included comments such as, 'The sonographer was so lovely with every scan I had and helped me throughout', 'What a lovely experience it was, thank you for making it so special for my husband and me', 'Massive thank you on behalf of my husband and myself for fitting us in last Thursday, it really put our minds at ease and the experience was absolutely amazing'.
- One letter described how the sonographer had picked up an issue with the baby on the scan and encouraged the woman to speak to their midwife or consultant obstetrician. She was then referred to a specialist hospital during her pregnancy, and the baby was treated immediately after birth. The woman commented, 'I have recommended the practice to friends and I will continue to do so'.
- The service also gathered patient feedback from social media, examples of comments included, 'Very professional', 'Took a lot of time to make sure I got what I need to get from my appointment', 'Felt so looked after each time'.

Emotional support

- **Staff provided emotional support to women 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.
- Due to the nature of the services offered at the clinic, there was no further involvement with ongoing care. In the case of miscarriage, the service always gave a leaflet from the miscarriage association. There was a team of therapists working at the clinic and a leaflet from their service was given to the woman if the

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sonographer felt it was appropriate and the woman required more support. For example, acupuncture for fertility, hypnobirthing, and birth-related anxiety. The sonographer also encouraged women to contact their midwife or hospital for further support, if required.

- The manager told us that if a woman became distressed in a public area, such as the waiting room, they found a quiet, private room for them, and they were supported by a member of staff.

Understanding and involvement of patients and those close to them

- **Staff involved women and those close to them in decisions about their care and treatment.**
- Staff took the time to explain the procedure to the woman before and during the ultrasound scan. Staff adapted the language and terminology they used when discussing the procedure with women and their families. We spoke with one woman and their partner who confirmed this. They told us that the sonographer explained what was happening throughout their appointment. The woman felt comfortable and understood everything she was told. She told us that the staff made sure she was aware of what to do next, for example contacting her midwife or GP if there were any further problems. They felt staff were caring, calming, reassuring and very flexible to her needs. The woman said that staff always fitted them in for an appointment at very short notice.
- The clinic manager told us that partners, carers and representatives of the women were welcome to attend the appointments. We spoke to one relative, who said that they felt involved in the care given.
- We saw a patient involvement policy and procedure, which described how women were enabled to express views and be involved in decisions about care and treatment.
- Women were always given their results at the end of their appointment. A woman said that she always had her results before she left the clinic and they had been explained to them in a way she could understand.

Are diagnostic imaging services responsive?

We have not previously rated this service. At this inspection, 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 clinic had a lot of different therapy services running from the location, from baby massage to acupuncture.
- The facilities and premises were appropriate for the services delivered; there was a comfortable waiting area, which contained children's toys, a variety of magazines including ones suitable for men, and a water cooler with cups. There was a patient toilet next to the waiting room, which contained a baby changing station.
- There was a small car park to the rear of the building and the clinic was located close to public car parks and transport.
- Women were given information relevant to their appointment, for example, needing a full bladder, when booking. This was then also sent in an email.
- The clinic offered a range of appointments; there were evening clinics on a Thursday evening and Saturday morning. Other clinics were held in the morning, over lunch time or in the afternoon. If a woman was unable to come to one of the arranged clinics, and the clinic manager was working in the building, the manager would often see the women at very short notice. Some women (fertility patients) required scans on a particular day. If possible, the service would book an appointment to suit the woman's timings. This may have meant starting a clinic early or extending the clinic.

Meeting people's individual needs

- **The service took account of women's individual needs.**
- Women's relatives or friends were sometimes used as interpreters by staff when English was not the woman's first language. We were concerned that these

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women may not fully understand what the scan would involve or their scan results, and as a result, informed consent could not be appropriately sought by the sonographers. Following the inspection, the manager told us that they had implemented a telephone interpreting service for staff to use, if required.

- There were steps leading up to the front entrance of the outside of the building and from the reception to the clinic room. For women who needed step free access, there was an entrance at the back of the building leading from the car park to the waiting area. There were no steps between the waiting area and the clinic room. There was also a moveable ramp.
- There were no specific adjustments for very overweight women, there was a moveable couch but no hoist. If a woman required the use of bariatric equipment, they would be referred to the NHS.
- All women accessed the clinic on a voluntary basis by telephone, email or in person. Appointments could be made by the woman, relative, friend or carer.
- Staff did not know if a woman had a learning disability before they arrived at the clinic; however, they told us that they would spend more time supporting women who may have a learning disability.
- All treatments and scans were undertaken in private consulting rooms with reasonable space for any additional relatives/friends or carers accompanying the woman. If a woman was required to undress, locked doors and curtains were used to protect her privacy.

Access and flow

- **Women could access the service when they needed it.**
- In the most recent patient survey, conducted in September 2018, all 24 women who completed the survey said that they had a choice of appointment times, except one who did not want a choice. No one said they had to wait to be seen when they arrived at the clinic.
- There was no waiting list or backlog at the clinic. Access to scan clinics was by appointment only. Same day appointments were usually available, if the clinic was full, an appointment was offered for another day.

- There was a range of appointments, including an evening and weekend clinic. The manager was extremely flexible and if they were working in the building, they would undertake a scan.
- The clinic did not formally monitor rates of non-attendance; they would access this information if there was a trend or increase. There was a very low rate of non-attendance because the clinic requested a deposit payment on booking the appointment. In the last year, there had been two women who had not attended their appointment. If a woman did not attend, a receptionist would contact her to find out why.
- From August 2017 to August 2018, no procedures/ examinations were cancelled for non-clinical reasons and no procedures/ examinations were delayed due to non-clinical reasons.

Learning from complaints and concerns

- **The service treated concerns and complaints seriously, investigated them and learned lessons from the results, and shared these with all staff.**
- The service had a current complaint policy that stated that complaints should be acknowledged within three working days and confirm how long the investigation would take. They aimed to resolve all complaints within ten working days but no longer than 20 working days.
- From September 2017 to September 2018, the service received one complaint. We saw that the complaint was acknowledged promptly, investigated, and closed within the required timescale. Action was taken promptly to resolve this.
- Information on how to make a complaint was available on the clinic website and in the clinic. Most complaints were made by email or telephone.
- If a woman made a complaint whilst still in the clinic, steps were taken to resolve it immediately. If this was not possible, details were taken for the manager to contact the woman. The registered manager was the individual responsible for overseeing the management of complaints.
- Learning from complaints was fed back to staff at their team meetings.

Diagnostic imaging

Are diagnostic imaging services well-led?

Requires improvement 

We have not previously rated this service. At this inspection, we rated well-led as **requires improvement**.

Leadership

- **The clinic manager had the skills, experience, and integrity needed to run a sustainable service.**
- There was an awareness of the service's performance, limitations, and the challenges it faced. The clinic manager was also aware of the actions needed to address those challenges.
- The sonographers reported to the clerical manager for matters of administration and to the clinic manager for clinical matters. The receptionists reported to the clerical manager, who in turn reported to the clinic manager.
- Staff knew the management arrangements and told us they felt well supported.
- All staff spoke overwhelmingly positive about the managers of Verulam Clinic. They said the managers were friendly, approachable, and effective in their roles. Staff felt confident to discuss any concerns they had with them.
- The clinic manager maintained their skills and knowledge through continuing with clinical practice and working as the main sonographer for the service. They were easily contactable for any queries or discussion needs that arose.

Vision and strategy

- **Verulam Clinic had a clear vision and strategy for what they wanted to achieve, with quality and sustainability as the top priorities.** Their vision was:
- To offer a high level of service and care for ultrasound and complementary healthcare services at a convenient location, within walking distance of the town and close to public transport and car parks.
- To provide a high-quality ultrasound scan service to women and their partners at times to suit them, and

to enhance the experience of pregnancy through personal service giving each woman enough time to understand and discuss the issues that are important to them.

- To provide women undergoing fertility treatment abroad accurate and timely scans with clear communication with their treatment clinic.
- To give clearly written reports to women following scans, which are also communicated to other healthcare professionals, such as GPs, in a manner appropriate to the test and with the permission of the woman and using encryption if supplied by a digital method.
- To provide an umbrella of complementary services from experienced professionals.
- The clinic manager told us they wanted to continue with the service they provided and grow it in a sustainable and measured way. This was reflected in the service's formal strategy which stated that the aim of Verulam Clinic was "to maintain the levels of patient numbers and when opportunity arises to increase them".
- The service planned to improve their online visibility by increasing and improving their social media marketing campaigns. They were also in the process of developing a new service website with an online booking option.
- Staff could articulate the vision and strategy for the service and understood their role in achieving them. The service strategy was discussed at the monthly team meetings and staff were involved in improving the service's online coverage.

Culture

- **Managers promoted a positive culture that supported and valued staff, creating a sense of common purpose based on shared values.** This was evident during our inspection.
- We spoke with four members of staff who all spoke positively about the culture of the service. Staff felt supported, respected, and valued, and all reported that they felt proud to work for Verulam Clinic. There was a sense of ownership and pride in the service provided.

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- The service operated an open and honest culture to encourage team working within the organisation. This was supported by the service's whistle-blower policy, dated October 2018.
- Any incidents or complaints raised would have a 'no blame' approach to the investigation. However, in circumstances where errors had been made, apologies would always be offered to the women, and staff would ensure steps were taken to rectify any errors. Staff were aware of the duty of candour regulation; however, they had not had any incidents which met the criteria where formal duty of candour had been required to be implemented.
- Action was taken to address behaviour that was inconsistent with the ethos of the service, regardless of seniority. The clinic manager used an external human resources consultancy firm to support them to manage poor staff performance, if required. They also sought advice from the Federation of Small Businesses.
- During and after our inspection, we informed the clinic manager that there were areas of the service that required improvement. They responded positively to this feedback and immediately put actions in place, demonstrating an open culture of improvement.
- While the service did not hold formal clinical governance meetings, staff meeting minutes demonstrated that complaints, patient feedback, and service changes were discussed and reviewed. The clinic manager told us informal discussions with staff were also held in between the team meetings.
- Although timely action was taken to address the concerns identified during our inspection, we were not assured that the service always kept themselves up-to-date with the most recent national and statutory legislation, such as national requirements regarding safeguarding training.
- At the time of our inspection, there was not a robust process in place to identify staff's learning needs as there was no formal appraisal system in place. Similarly, Verulam Clinic did not know what training the sonographers had completed at their substantive NHS employer. This meant we could not be assured that Verulam Clinic had full oversight of the competencies, skills and capabilities of staff working for their service. We raised these concerns to the clinic manager during our inspection, who told us they would review these processes. Following our inspection, we were provided with assurance that the clinic manager had commenced staff appraisals. A copy of the sonographers' mandatory training matrix had also been requested from their substantive employer.
- While the clinic manager believed the sonographers had received training on information governance, basic life support, infection prevention and control, consent and mental capacity at their substantive employer, there was no evidence to support this. Similarly, we were not assured that the clinic manager had completed all the relevant training.
- Verulam Clinic did not require individual sonographers to hold their own indemnity insurance as they were covered under the service's insurance.
- All therapists who worked at the clinic on a self-employed basis had professional indemnity insurance in place.

Governance

- **The arrangements for governance were clear, generally operated effectively, and were appropriate to the size of the service. However, Verulam Clinic did not have full oversight of the competencies, skills and capabilities of staff working for their service. We were also not assured that the service always kept up-to-date with important national and statutory legislation.**
- The clinic manager had overall responsibility for clinical governance and quality monitoring. This included investigating incidents and responding to patient complaints.
- There were no incidents reported by the service within the last 12 months. This meant it was not possible to accurately assess how learning from incidents was embedded. However, staff assured us that significant events would be discussed during team meetings.

Managing risks, issues, and performance

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- **While the service generally had effective arrangements in place for identifying and recording risks, there was little evidence that these risks and their mitigating actions were discussed with the wider team.**
- The service did not hold a risk register; however, risk assessments were completed for any identified risks. At the time of our inspection, seven risk assessments had been undertaken, including assessments for slips and trips, and unauthorised people entering the building.
- All staff we spoke with could clearly articulate the main risks to the service and what was being done to address them. Staff felt the biggest risk to the service was patient footfall. However, at the time of our inspection, this had not been risk assessed. Following our inspection, a risk assessment was completed, and mitigating actions included; increasing presence on social media sites and introducing a new website.
- We identified a risk relating to carpeted flooring in the clinic rooms, which had not been formally risk assessed by the service. Despite this, the clinic manager had already acted to mitigate this risk by having the carpets deep cleaned every six months. After our inspection, the clinic manager completed a risk assessment which confirmed the mitigating actions.
- Risk assessments were completed on a standard template to ensure consistent information was used. All templates had the risk identified, mitigating/control measures and the individual responsible for managing the risk. Although the risks included review dates, there was no evidence that risks, and their mitigating actions were discussed in any of the staff meeting minutes we reviewed. Therefore, we could not be assured the service was taking timely and appropriate action to address the risks within the service.
- The service did not use key performance indicators to monitor performance. However, the service used patient feedback, complaints, and clinical audit results to help identify any necessary improvements and ensure they provided an effective service.
- Prior to our inspection, the service had initiated an annual clinical audit programme. Clinical audits were

completed at least three times a year and audited local practice against national guidance. On the most recent audit, the results demonstrated that staff did not always print enough scan images to evidence the conclusions made in their scan reports. We saw the service took appropriate action to address these audit results.

Managing information

- **The service managed and used information to support its activities, using secure electronic systems with security safeguards.**
- The service was aware of the requirements of managing a woman's personal information in accordance with relevant legislation and regulations. General Data Protection Regulations (GDPR) had been reviewed to ensure the service was operating within them.
- Verulam Clinic was registered with the Information Commissioner's Office (ICO), which is 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.
- Patient records and scan reports were accessed easily but were generally kept secure. Paper records were stored in locked filing cabinets and staff locked computer terminals when not in use. However, we found four records stored in an unlocked draw in the kitchen of Verulam Clinic. The records included personal details, ultrasound scan reports and scan images. We raised this as a concern to the clinic manager who removed the records immediately and stored them in a locked cupboard in the clinic office.

Engagement

- **The service engaged well with women, staff, the public and local organisations to plan and manage appropriate services and collaborated with partner organisations effectively.**
- Women's views and experiences were gathered and used to improve service provision. The service ran an annual patient satisfaction survey for women and their relatives to give their feedback about their

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experience. The results from the latest survey, completed in September 2018, was overwhelmingly positive with 100% of women reporting they would definitely recommend the service to others.

- There was a website for members of the public to use. This held information regarding the services offered. There was also information about how women could provide feedback regarding their experience. Similarly, women were encouraged to leave feedback on the service's social media pages. For example, one woman commented, "the team are faultless and make you feel completely comfortable and offer a professional, enjoyable experience of bonding with your unborn baby".
- We saw that patient feedback was taken seriously and used to improve the service. For example, following patient feedback, the service introduced a Thursday evening clinic.
- Results from the patient satisfaction survey and patient complaints were discussed with the team during staff meetings.
- Team meetings were held monthly, and staff told us that the meetings helped to make them feel actively

engaged in service planning and development. We reviewed the last three team meeting minutes held in September 2018, October 2018, and November 2018, and saw that changes to service provision, complaints, patient feedback, and clinic maintenance were discussed. The minutes were circulated to all staff after the meeting. This ensured that staff who were not present were kept informed about any changes.

- Verulam Clinic staff had formulated positive relationships with the therapists, who worked out of the clinic on a self-employed basis. Staff had created social media groups to help engage with each other. Within these groups, staff promoted specific related topics and updated information for others to be aware of.

Learning, continuous improvement and innovation

- Staff could provide examples of improvements and changes made to processes based on patient feedback, incidents, and staff suggestion.
- The clinic manager took immediate and effective actions to address some of the concerns we raised during the inspection.

Outstanding practice and areas for improvement

Areas for improvement

Action the provider **MUST** take to improve

- The provider must ensure there is an effective process to assure them of the competencies, skills and capabilities of staff working for their service.
- The provider must ensure there is a rolling mandatory training programme for staff.
- The provider must ensure they are aware of the most up-to-date national and statutory legislations that may affect their service and implement any changes in a timely manner.

Action the provider **SHOULD** take to improve

- The provider should consider how risks and their mitigating actions are discussed with the wider team.
- The provider should consider carrying out regular hand hygiene audits to monitor and improve infection prevention and control practices.
- The provider should consider implementing Mental Capacity Act (2005) training and mental capacity assessments, when required.

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	<p>Regulation 17 HSCA (RA) Regulations 2014 Good governance</p> <p>How the regulation was not being met:</p> <ul style="list-style-type: none">• Staff did not receive mandatory training in key skills after their initial induction to the service.• There was no oversight on what training the sonographers had completed at their substantive employer.• Managers did not formally appraise staffs' work performance.• The service did not always keep up-to-date with important national and statutory legislation.