

Elms Medical Practice

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

Elms Medical Practice is operated by STAHMIS Ltd. The service is consultant-led and provides diagnostic imaging services (ultrasound scans) to NHS patients who attend GP practices within St. Albans, Harpenden, and the surrounding areas. The aim of the service is to see patients within their local community to prevent them from waiting for an NHS hospital appointment.

We inspected this service using our comprehensive inspection methodology. We carried out an announced inspection on 8 October 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.

The main service provided by Elms Medical Practice is diagnostic ultrasound scans.

Services we rate

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

We found the following areas of good practice:

- Staff were caring, kind and engaged well with patients.
- Services were planned in a way that met the needs of patients and the local community. Patients were offered a choice of appointments in three locations within their local community.
- Staff recognised incidents and knew how to report them. All incidents were investigated and lessons learned were shared across the team.
- Managers promoted a positive culture that supported and valued staff. Staff confirmed they felt respected and valued.
- The service had arrangements in place to manage risks to patients. Patient referrals were screened against set criteria, which had been shared with local GPs.
- Staff understood their responsibilities regarding consent, and consent was undertaken in line with national guidance and the service's consent policy.

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

- There was no evidence that peer review audits of the ultrasound images and reports were undertaken, as recommended by the British Medical Ultrasound Society (BMUS).
- Personnel files for the consultant radiologists were incomplete, which meant we could not be assured that the radiologists were suitable and competent for their role. This was addressed by the service following our inspection.
- There was no formal arrangement in place to ensure STAHMIS Ltd was informed of any performance problems or other concerns relating to a consultant's practice. Following our inspection, the service improved their management of practising privileges.
- The service did not have a robust governance framework. Clinical governance and director meetings were not held consistently and the service did not review and share audit results.

Summary of findings

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. 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 imaging core service, was the only core service provided at this service. We rated the service as good overall because staff were aware of their roles and responsibilities to report, investigate and learn from incidents. There was a system and process in place for identifying and reporting potential abuse. Processes were in place for the escalation of unexpected findings during ultrasound scans. Feedback from patients was very positive. Appointments were scheduled to meet the needs and demands of patients who required their services and the STAHMIS manager had the appropriate skills and experience to manage the business.

However, we identified concerns with the process of managing, reviewing and granting practising privileges. There was also not a system in place to ensure risks to the service were regularly reviewed. There was no evidence that peer review audits were completed, as recommended by the British Medical Ultrasound Society.

Summary of findings

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Good



Elms Medical Practice

Services we looked at

Diagnostic imaging

Summary of this inspection

Background to Elms Medical Practice

Elms Medical Practice is an independent diagnostic service based in Harpenden, Hertfordshire, and is operated by STAHMS Ltd. It serves the communities of Harpenden, St. Albans, and the surrounding areas. STAHMS Ltd was established approximately 10 years ago in response to some of the health economy's most pressing challenges. The aim of the service was to help reduce waiting times, speed up diagnoses, improve patient pathways and enhance the overall patient experience.

STAHMS Ltd operates three locations across Harpenden and St. Albans, including Elms Medical Practice, The Colney Medical Centre, and the Hertfordshire Clinic.

STAHMS Ltd is commissioned by the local clinical commissioning group (CCG) to provide diagnostic

imaging services (ultrasound scans) to NHS patients who attend the local GP practices. The aim of Elms Medical Practice is to see patients within their local community to prevent them from waiting for an NHS appointment and to reduce the pressures faced by the local NHS trusts. Services are provided from a clinic room, situated in a GP surgery, which is managed by a different provider.

The service has not had a registered manager in post since September 2017. However, at the time of our inspection, a new manager had recently been appointed and had applied to register with the CQC.

Elms Medical Practice is registered with the CQC to undertake the regulated activity of diagnostic and screening procedures. This was the first inspection of the service since it registered with the CQC in 2015.

Our inspection team

The inspection team was comprised of a CQC lead inspector and a specialist advisor with expertise in radiological services. The inspection team was overseen by Phil Terry, Inspection Manager, and Bernadette Hanney, Head of Hospital inspection.

Information about Elms Medical Practice

The service was consultant-led and provided diagnostic imaging services (ultrasound scans) to NHS patients who attended the GP practices within St. Albans, Harpenden, and the surrounding areas. The aim of the service was to see patients within their local community to prevent them from waiting for an NHS hospital appointment. Elms Medical Practice provided diagnostic ultrasound scans only. It was registered to provide the following regulated activities:

- Diagnostic and screening procedures.

The service offered most types of ultrasound scans, including kidney, ureter, bladder, abdominal, pelvic,

trans-vaginal, testes, vascular and thyroid and parotid glands scans. They did not offer breast, cardiac, obstetric, or doppler scans. Patient appointments were made through referrals directly from the patient's GP.

At the time of our inspection, STAHMS Ltd employed two directors, a STAHMS manager, four part-time clinic assistants/administrators, and a service manager, who was responsible for determining the necessary office hours, clinic assistant cover and relevant chaperones. Seven consultant radiologists also worked for STAHMS Ltd under practising privileges, including the clinical lead. All staff worked across the three locations, as required. Temporary support had also been sourced to assist the STAHMS and service managers.

Summary of this inspection

Elms Medical Practice was run from a clinic room in a GP surgery, which was operated by a different provider. Elms Medical Practice had a service level agreement for the use of this clinic room to perform ultrasound scans. The GP surgery managed the premises; however, one ultrasound scanner and equipment belonged to the Elms Medical Practice.

Standard operational hours were Monday and Wednesday mornings, Thursday afternoon and all-day Friday.

During our inspection, we visited the headquarters for STAHMIS Ltd in St Albans and the Elms Medical Practice in Harpenden. We spoke with seven staff members, including a consultant radiologist, the STAHMIS and service managers, clinic assistants and one of the directors. We also spoke with three patients and reviewed five 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. This was the service's first inspection since registration with CQC.

Activity (2017/18):

- STAHMIS Ltd performed a total of 8,340 ultrasound scans for this reporting period.
- From March to August 2018, the Elms Medical Practice completed 2,246 ultrasound scans.
- All patients were NHS-funded.
- For the reporting period of August 2017 to August 2018, STAHMIS Ltd cancelled 260 appointments all for non-clinical reasons.

Track record on safety:

- The service reported zero never events September 2017 to August 2018.
- The service had recorded two incidents from October 2017 to September 2018, all graded as no harm.
- The service reported zero serious injuries reported from September 2017 to August 2018.
- The service received six complaints from July 2017 to July 2018.
- STAHMIS Ltd received three written compliments from July 2017 to July 2018.
- STAHMIS Ltd reported zero incidents of health associated MRSA, Methicillin-sensitive staphylococcus aureus (MSSA), Clostridium difficile (C.diff), and Escherichia coli (E-Coli).

Services provided at the Elms Medical Practice under service level agreement:

- GP surgery (premises, cleaning reception staff and consumable items, such as gloves and aprons)
- The text messaging appointment reminder service
- Maintenance of the ultrasound machines and equipment
- E-radiology learning tool
- The electronic patient information system

Summary of this inspection

The five questions we ask about services and what we found

We always ask the following five questions of services.

Are services safe?

We rated safe as good because:

- There was good compliance with mandatory training across the service.
- Staff understood the need to protect people from abuse and they had all completed safeguarding training at the required level to ensure they had the appropriate knowledge to do so.
- Standards of cleanliness and hygiene were well maintained.
- The service had suitable equipment and maintained it appropriately.
- The service had arrangements in place to manage risks to patients. Patient referrals were screened against set criteria, which had been shared with local GPs.
- The service had sufficient staff, of an appropriate skill mix, to enable the effective delivery of safe care and treatment.
- Scan reports were comprehensive and sent to the patient's GP within 48 hours of the appointment.
- Staff recognised incidents and knew how to report them. All incidents were investigated and lessons learned were shared across the team.

However:

- Staff did not have instant access to a patient's previous ultrasound image.
- Hand hygiene audits were not undertaken to measure staff compliance with the World Health Organisation's (WHO) 'Five Moments for Hand Hygiene.'

Good



Are services effective?

We currently do not rate effective, we found:

- There was no evidence that peer review audits of the ultrasound images and reports were undertaken, as recommended by the British Medical Ultrasound Society (BMUS).
- There were no local clinical protocols or policies for staff to follow, which were based on national policies or best practice guidance, including those released by bodies such as the National Institute for Health and Care Excellence (NICE) and BMUS.
- Service policies did not always contain a completion or next renewal date. However, this was escalated and rectified after our inspection.

Summary of this inspection

- Although staff had the appropriate qualifications for their role within the service, we could not be assured that the radiologists were suitable and competent for their role.

However:

- Staff understood the principle of assessing mental capacity and best interest decisions but they had not needed to apply this knowledge.
- All staff files reviewed contained evidence of disclosure and barring service checks.
- Staff understood their responsibilities regarding consent and we saw consent was undertaken in line with the service consent policy.

Are services caring?

We rated caring as good because:

- We observed all staff treating patients with dignity, kindness, compassion, and respect.
- Staff understood the impact that a patient's care, treatment, or condition had on their wellbeing and on their relatives, both emotionally and socially.
- We observed staff communicating with patients so that they understood their care, treatment, and condition.
- Staff recognised when patients and those close to them needed additional support to help them understand and be involved in their care and treatment.

Good



Are services responsive?

We rated responsive as good because:

- Information about the needs of the local population was used to inform how services were planned and delivered. Patients were offered a choice of appointments in three locations within their local community.
- The clinical environment was suitable and appropriate to meet the needs of the patients.
- An interpretation service was available for patients whose first language was not English.
- People could access the service when they needed it. Waiting times from referral to receiving the ultrasound scan were in line with good practice.
- Information on how to raise a concern or a complaint was available. Complaints and concerns were responded to in line with the service's complaints policy.

However:

Good



Summary of this inspection

- Clinic assistants had not received training to support them to care for patients with dementia, mental health concerns, or learning difficulties.
- Patient feedback indicated that some patients felt they did not receive adequate information about what their scan would involve prior to their appointment.

Are services well-led?

We rated well-led as requires improvement because:

- Whilst the service had arrangements in place for identifying and recording risks, there was no evidence that these risks were reviewed in a timely manner.
- There was not a robust governance framework in place. Clinical governance and director meetings were not held consistently and did not review and share audit results.
- The service did not have a robust process for reviewing, managing, and granting practising privileges. There was no formal arrangement in place to ensure STAHMIS Ltd was informed of any performance problems or other concerns relating to a consultant's practice. Following our inspection, the service improved their management of practising privileges.

However:

- Leaders had the skills, knowledge, experience and integrity needed to run a sustainable service.
- While staff were not able to fully articulate the vision for the service, staff worked within the ethos of it.
- Managers promoted a positive culture that supported and valued staff. Staff confirmed they felt respected and valued.
- Electronic patient records were kept secure to prevent unauthorised access to data.
- Patients' views and experiences were gathered and acted on to shape and improve the service and culture.
- Staff felt actively engaged with the service development and planning, and were kept well informed about the potential closure of the service.

Requires improvement







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

Diagnostic imaging

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

Are diagnostic imaging services safe?

Good 

We have not previously inspected this service. We rated safe as **good**.

Mandatory training

- The service provided mandatory training courses in key skills to staff, which included 'face-to-face' and 'e-learning' training modules. Staff within the service understood their responsibility to complete mandatory training.
- The mandatory training topics for the clinic assistants covered key areas, such as basic life support, chaperone training, information governance, customer care, equality and diversity, health and safety, infection prevention and control, safeguarding adults, and safeguarding children training.
- At the time of this inspection, the clinic assistants were 100% compliant with all the training modules listed above, apart from one. Two of the five clinic assistants had not completed their customer care training, which gave a compliance rate of 60%.
- The consultant radiologists working for STAHMIS Ltd under practising privileges did not receive mandatory training from the service. However, they received training from their substantive place of employment and STAHMIS Ltd kept a record of their training completion in their individual staff files.

Safeguarding

- Staff understood the need to protect people from abuse and they had all completed safeguarding training at the required level to ensure they had the appropriate knowledge to do so.
- We reviewed the staff training files and found that all seven of the consultant radiologists were compliant with safeguarding adults training level two.
- The training files also showed that all the clinic assistants were compliant with adults safeguarding level one training, which was the level appropriate to their role.
- The service occasionally saw patients who were under the age of 18. From review of staff files, we saw that all the clinic assistants had received safeguarding children's training appropriate to their role. We also found that six of the seven consultant radiologists had completed safeguarding children's level three training. This met the intercollegiate guidance 'Safeguarding Children and Young People: roles and Competencies for Healthcare Staff' (March 2014). One consultant radiologist had not completed safeguarding children's training. However, this individual did not see or treat patients under the age of 18 years.
- The service had up-to-date safeguarding adults and children's policies in place, which reflected relevant legislation and local requirements, including the contact details of the local safeguarding boards. Contact numbers for making safeguarding referrals were also displayed in the clinic room at the Elms Medical Practice.

Diagnostic imaging

- The service had a designated lead for both children and adults safeguarding, who was available during working hours to provide support to staff. The safeguarding lead was one of the GP directors and had completed safeguarding level three training.
- Staff we spoke with had not made any safeguarding referrals; however, they were able to confidently tell us how they would identify a safeguarding issue and what action they would take. This included informing the safeguarding lead for the service.
- Staff we spoke with were aware of the Department of Health female genital mutilation and safeguarding guidance for professionals' (March 2016). If staff were concerned about any patients, they would refer to the local safeguarding team.

Cleanliness, infection control and hygiene

- Standards of cleanliness and hygiene were maintained and the clinic room was visibly clean and clutter free on the day of our inspection. STAHMIS Ltd had infection prevention and control (IPC) policies and procedures in place, which provided staff with guidance on appropriate IPC practice.
- The GP surgery was responsible for the cleaning and maintenance of the clinic room and surgery. This was confirmed in the service level agreement between STAHMIS Ltd and the surgery. However, the clinic team was responsible for cleaning the patient couch and ultrasound machine at the end of each clinic list. Cleaning was recorded on a daily check sheet, which was reviewed by the service manager at the end of each week. We reviewed the cleaning checklists for the Elms Medical Practice from 17 August to 8 October 2018, and saw that daily cleaning had been completed.
- Staff told us that it was extremely rare for there to be problems with the cleanliness of the rooms they used. However, if they identified any concerns they would inform the service manager, who raised this with the GP practice manager. We saw evidence of this on one of the cleaning checklists we reviewed.
- STAHMIS Ltd undertook an annual infection control inspection of the GP practice. We reviewed the results from the latest inspection completed in December 2017, which did not identify any concerns with the cleanliness of the surgery, waiting area or clinic rooms. The inspection also found that there was an adequate supply of personal protective equipment (PPE) and hand sanitising gel.
- The service manager undertook deep cleaning of the ultrasound machine every six months. We reviewed the deep cleaning records from 17 January and 13 July 2018 and found no concerns were identified during the deep cleaning process.
- A supply of PPE, which included gloves and aprons were available and accessible in the clinic room. We observed staff using the PPE appropriately when interacting with patients and all staff 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. The patients we spoke with also confirmed that staff washed their hands prior to attending to them. Hand sanitiser gels were available in the clinic room.
- Hand hygiene audits were not undertaken to measure staff compliance with the World Health Organisation's (WHO) 'Five Moments for Hand Hygiene.' These guidelines are for all staff working in healthcare environments and define the key moments when staff should perform hand hygiene to reduce risk of cross contamination between patients. We raised this as a concern during our inspection. We were told that the service did undertake hand hygiene checks as part of their annual infection control inspections. However, we reviewed the results from the latest inspection, and found no evidence that staff's competency or compliance were sufficiently assessed.
- The ultrasound probe was cleaned in front of the patient and a latex-free sheath was placed over the probe. At the end of each procedure, the couch was cleaned and prepared for the next patient with clean paper.
- Waste was handled and disposed of in a way that kept people safe. Staff used the correct system to handle and sort different types of waste.
- There had been no instances of healthcare acquired infections from September 2017 to August 2018.

Environment and equipment

Diagnostic imaging

- The service had suitable equipment and maintained it appropriately.
- The service's risk register contained one risk relating to the age of the ultrasound machines, which had been graded as a 'moderate' risk. We saw there were actions in place to mitigate this risk, which included:
 - Consultant radiologists referred patients to another clinic or their local NHS acute trust for a repeat scan if there were any concerns about the quality of the ultrasound image.
 - 24/7 new for old cover on the parts of the ultrasound machine.
 - Six-monthly servicing of the ultrasound machines.
- At the time of our inspection, there were no plans to replace the ultrasound machines. This was because STAHMIS Ltd had not renewed their contract with the local clinical commissioning group (CCG), so would not be providing diagnostic services past March 2019.
- Resuscitation equipment, for use in an emergency, was accessible in the GP practice. The resuscitation trolley was owned and checked by staff within the GP practice; however, STAHMIS staff knew where the trolley was located.
- Service records for the ultrasound machine at the Elms Medical Practice confirmed it had been serviced every six months, the last completed in August 2018. The service that had been undertaken in March 2018 identified concerns with the ultrasound probe. We saw evidence that the probe was replaced immediately. In addition, 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 was small but well arranged by the service. Staff turned the lights off when undertaking a scan to darken the room. This meant the scans could be observed clearly.
- The waiting room for the service was the GP surgery main waiting room. This waiting room was light and airy, with adequate seating available. A patient toilet was accessible close to the clinic room.

- We observed fire notices in the clinic room door indicating the nearest exit and protocol for evacuation.

Assessing and responding to patient risk

- The service had arrangements in place to manage risks to patients.
- The service accepted patients who were physically well and could transfer themselves to a couch with little support. The lack of a hoist in the clinic room meant patients who were not able to transfer themselves, would be re-referred to an appropriate centre that could cater for less mobile patients.
- Patient referrals were screened against set criteria, which had been developed and agreed by the consultant radiologists. GPs were given the criteria, called the 'iTriage', to follow when requesting a patient to be scanned. Once a referral was sent, the clinic assistants conducted a 'vetting of the request', where they checked the referral for completeness and verified it was within the agreed inclusion criteria. When it fell outside of the criteria, the clinic assistants passed it to the appropriate consultant for review. The consultant could then request additional information from the referrer, reject the referral, or recommend a more appropriate investigation or service.
- If the service received any referrals that were missing key information, such as date of birth or clinical history, the clinic assistants contacted the referrer and asked for further information prior to booking the patient appointment.
- When urgent referrals were received, the service's electronic booking system would not allow the clinic assistants to book routine appointments until the urgent referral had been acknowledged.
- The service had a 'First Aid Policy' dated January 2018, which provided clear guidance on what action staff should take in the event of a patient or visitor feeling unwell or deteriorating during their appointment. If staff had concerns about a patient's condition during their ultrasound scan, the radiologist would stop the scan, call for help and telephone 999 for emergency support.
- Both the clinic assistants and the consultant radiologists were trained in basic life support (BLS),

Diagnostic imaging

and would put their training to use until the ambulance arrived. Training records showed that all staff were compliant with this annual training requirement. BLS training gives staff a basic overview of how to deal with a patient who may have stopped breathing, such as starting cardiopulmonary resuscitation.

- In addition, the clinic room at the Elms Medical Practice contained surgery-specific guidance on what action staff should take if a patient deteriorated.
- From October 2017 to September 2018, the service had not reported any incidents that related to staff having to call for an ambulance.
- While the service did not formally use the 'Paused and Checked' checklist devised by the British Medical Ultrasound Society and Society of Radiographers, we saw that the radiologist completed most of the checks during their patient appointments. For example, we observed the radiologist:
 - Checked the referral documentation and patient notes
 - Confirmed whether the scan was justified
 - Confirmed the patient's identity
 - Confirmed the area to be scanned
 - Gained patient consent
 - Provided clear information and instructions to all involved, including the potential limitations of the ultrasound scan
 - Informed the patient how they would find out about the scan results
 - Informed the referrer of any urgent or significant findings
- Scan reports were completed immediately after the scan had taken place, which we observed during our inspection. If there were any abnormalities detected, the clinic assistant or consultant radiologist emailed the results to the relevant GP surgery immediately and asked for the GP to respond confirming receipt of the report. If they did not receive a response, the clinic assistant called the relevant referrer and informed them of the urgent report.

- All seven of the consultant radiologists worked at the local NHS trust. This meant they could request further urgent diagnostic tests, such as a computerised tomography (CT) scan. This prevented the patient waiting for their GP to make the referral on their behalf.
- Radiologists working out of the Elms Medical Practice did not have instant access to a patient's previous ultrasound image. This was because all previous scan images were stored at the service's headquarters in St. Albans. However, the clinic assistants, who were responsible for booking patient appointments, would not book a patient for a follow-up scan at this location where possible. The radiologists also told us they would delay reporting on the ultrasound image until they had checked the previous scan image, if required.
- The service only used latex-free covers for the transvaginal ultrasound probe, which minimised the risk of an allergic reaction for patients with a latex allergy.

Staffing

- The service had sufficient staff, of an appropriate skill mix, to enable the effective delivery of safe care and treatment on the day of our inspection.
- There were five part-time clinic assistants who also performed administrative tasks, such as booking appointments and arranging clinics. This included the service manager, who was responsible for producing staff rotas and managerial processes.
- 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 consultant radiologist and a clinical administrator. 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.
- The service did not use locum staff, bank staff, or agency staff. In the event of a staff member going off sick, the clinic assistants would cross-cover between themselves. In circumstances where this was not possible, a member of the management team covered the clinic assistant role. This helped to prevent clinic cancellations.

Diagnostic imaging

- From October 2017 to September 2018, the service reported a sickness rate of 0.4%.
- There was a risk on the risk register relating to the staff vacancy rate, which had been graded as a 'moderate' risk by the service. We saw that actions had been taken to mitigate this risk, which included recruiting an additional clinic assistant to fill the vacancy. At the time of the inspection, the service had recently appointed a clinic assistant to this post. They were due to start imminently.

Medical staffing

- The service did not employ any medical staff, however, seven consultant radiologists worked under practising privileges. The granting of practising privileges is a well-established process within independent healthcare whereby a medical practitioner is granted permission to work in an independent hospital or clinic, in independent private practice, or within the provision of community services. All seven consultant radiologists worked for the local NHS trust.
- There was not a robust process in place to ensure the consultant radiologists were fit for practise and competent for their role. For example, the staff files did not contain evidence of appraisals, which had been completed by their substantive employer. Appraisals provide evidence that individuals still hold the necessary skills and competencies to undertake their role safely and effectively.
- The ultrasound clinics were scheduled in advance and the consultant radiologists assigned themselves to the clinics, which fitted around their permanent employment positions.
- The STAHMIS manager and two directors of the service were registered GPs.

Records

- Staff stored and updated individual patient care records in a way that protected patients from avoidable harm and maintained their confidentiality. Staff received training on information governance and records management as part of their mandatory training programme. At the time of our inspection, the service reported an 100% compliance rate with this training.

- The service used an electronic patient information system to receive referrals, book appointments, communicate with GPs and send their scan reports. Access to this system was password protected and meant patient records were stored securely.
- STAHMIS Ltd had a service level agreement with the provider of their electronic patient information system. The agreement confirmed STAHMIS Ltd would receive immediate support in the event of an electronic system failure.
- The GP surgery at Elms Medical Practice did not use the same electronic patient information system. Therefore, referral requests and the ultrasound scan reports were sent through a secure email portal.
- The consultant radiologist undertaking the ultrasound scan completed the scan report immediately after the patient's appointment. It was their responsibility to send the diagnostic report to the patient's referring GP within 48 hours of their appointment.
- The diagnostic reports were produced in accordance with the Standards for Reporting and Interpretation of Imaging Investigation (2018), published by the Royal College of Radiologists. We reviewed five electronic records during our inspection and saw they were accurate, complete, legible, and up to date. Each report included patient identification, reason for the scan, date of the scan and of the report, clinical information, the name of the referrer, radiologist and chaperone, as well as a description of findings, conclusions, and recommendations.
- Patient ultrasound images were stored on the ultrasound machine for approximately 20 working days before deletion. All scan images were backed up to a hard disc at the end of each clinic and stored at STAHMIS Ltd head office in St. Albans.

Medicines

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

Incidents

- STAHMIS Ltd had processes in place for staff to raise concerns and report incidents. Staff understood their roles and responsibilities to raise concerns and record safety incidents.

Diagnostic imaging

- Staff reported any incidents directly to the service manager via email or telephone. The service manager collated the incidents into an electronic log, which was used to identify any themes and learning. The log was used during governance and team meetings. Staff told us they received direct feedback when they reported an incident, and lessons learned from incidents were cascaded to the team during team meetings and clinical governance meetings. Meeting minutes confirmed this.
- All staff we spoke with described the process for reporting incidents and provided examples of when they would do this, such as information governance breaches.
- The service had an incident reporting policy, which set out the process for reporting an incident, the grading of incidents and the investigation process expected. The policy stated that the service manager was responsible for conducting investigations into all incidents.
- From October 2017 to September 2018, the service reported two incidents. Both incidents were graded as 'no harm'; however, the service still looked for opportunities to learn lessons from these incidents. For example, one incident related to an information governance breach where a patient's ultrasound report was sent to the wrong GP surgery. The staff member involved was new to the service and was provided with additional training on sending reports. In addition, a reminder was also sent to all clinic assistants about their responsibilities surrounding information governance.
- Elms Medical Practice did not report 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 we spoke with understood the duty of candour process and the need for being open and honest with patients when errors occur. Senior staff members could explain 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 service had a 'Being open and honest' policy in place.
- Senior staff were aware of the requirements for reporting serious 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 for diagnostic services.

Evidence-based care and treatment

- Whilst we observed that care and treatment was delivered in line with current legislation and nationally recognised evidence-based guidance, the service did not have any local clinical protocols for staff to follow, such as locally agreed examination protocols for each examination. However, if staff wanted to refer to national evidence-based guidance, they used an e-radiology learning tool, which they accessed via an 'app' (application) on their mobile phones. This app provided direct access to national guidance and legislation.
- Staff we spoke with demonstrated a good understanding of the national legislation that affected

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their practice, including guidance produced by the National Institute for Health and Care Excellence (NICE), the British Medical Ultrasound Society, and the Society of Radiographers.

- There was not a formal system in place to ensure staff were updated on changes to local policies, national guidance and patient safety alerts. Following our inspection, the STAHMIS manager informed us that guidance and legislation changes had been added as a standing agenda at the clinical governance meetings.
- Local policies did not contain a next renewal date. For example, we found the 'Vetting and Referral Criteria' policy did not contain a review or renewal date despite seeing evidence that it had been updated since publication in 2008. This meant we could not be assured that policies were reviewed in a timely manner. Following our inspection, we saw that the service had implemented a new policy front sheet for all of their policies. The front sheet included the original policy creation date, the renewal date, and the dates of all previous reviews.
- All staff we spoke with were aware of how to access policies, which were stored electronically on an internal computer drive at STAHMIS Ltd head office. If staff required access to a policy whilst working at the Elms Medical Practice, a colleague or the service manager would send a copy of the policy to them via their secure email network.
- We saw no evidence of any discrimination, including on the grounds of age, disability, gender, gender reassignment, pregnancy and maternity status, race, religion or belief, and sexual orientation when making care and treatment decisions.
- We observed the radiologist providing clear information to the patients about their ultrasound scans, including the potential limitations of the scan.

Nutrition and hydration

- To improve the quality of the image, patients having a renal scan were asked to drink two pints of water one hour prior to their appointment time.

- For certain types of scans, such as abdominal scans, patients were required to fast before their appointment to enable clearer imaging. Advice on fasting and drinking water was provided to patients by telephone when they booked their appointment.
- There was a drinking water dispenser in the waiting room of the GP surgery, which was accessible to patients and visitors.

Pain relief

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

Patient outcomes

- The service monitored patient outcomes through their annual patient satisfaction survey, waiting times, activity and "did not attend" audits. Service data was also collected, audited, and reported to the clinical commissioning group four times a year to monitor performance. This included information about clinic cancellations. For example, from August 2017 to August 2018, 260 appointments were cancelled across all three of the STAHMIS locations. All were cancelled due to non-clinical reasons, such as family bereavement or severe weather. The service responded by offering patients the next available appointment and added in additional clinics at the weekends to compensate.
- Although staff informed us that peer reviews of the ultrasound images and reports were completed as part of the clinical governance meetings at their local NHS trust, STAHMIS Ltd was unable to provide us with documentary evidence of this during our inspection. The service's clinical governance and director meeting minutes also did not provide us with assurances that results from completed peer reviews were formally fed back to STAHMIS Ltd. This meant we were unable to confirm whether these audits were being completed. This is not in line with the British Medical Ultrasound Society guidance, which recommends peer review audits are completed using the ultrasound image and the written report. We raised this as a concern to senior managers during our inspection. They told us

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that they had discussed this with the clinical lead, who was responsible for ensuring the audits were completed. The clinical lead had agreed to begin formally documenting this work.

- Senior managers told us they wanted to focus more on how their service improved the timeliness of patient diagnosis and treatment, rather than focusing solely on service performance, such as waiting times and 'did not attend' rates. However, they recognised that this would be difficult to monitor due to their limited oversight of what happens to patients after their scan.

Competent staff

- Staff had the appropriate qualifications for their role within the service; however, we could not be assured that the consultant radiologists working under practising privileges, were suitable and competent for their role.
- We reviewed the staff files for the consultant radiologists and found that two of the seven files did not contain evidence of two employment references. This meant we could not be assured effective recruitment processes had been followed and staff were of good character. The main reason given was that all the radiologists were known to the clinical lead from their work together within the local NHS trust.
- None of the seven consultant personnel files contained evidence of appraisals, which had been completed by their substantive employer. Appraisals provide evidence that individuals still hold the necessary skills and competencies to undertake their role safely and effectively. There was no formal arrangement in place to ensure STAHMIS Ltd was informed of any performance problems or other concerns relating to a consultant's practice. We raised this as a concern during our inspection, and we were told the service manager would regularly check the professional register for any indication of concerns. In addition, the clinical lead informally fed-back to STAHMIS Ltd about staff performance and competency. However, as there was nothing formally documented, we could not be assured these discussions took place and the consultant radiologists were suitable for their role. Following our inspection, the service implemented a 'Practising Privileges Agreement'. The agreement formally specified the ongoing obligations between the consultant radiologists and STAHMIS Ltd, and would be monitored through the newly introduced medical advisory committee (MAC). In addition, we saw evidence that the service now had a copy of the consultants' most recent appraisals in their staff files; they included this as an annual requirement on their staff file checklist.
- Consultant qualifications were recorded in their employment files, along with evidence of their professional registration, professional indemnity insurance and professional revalidation. Following our inspection, the service implemented a 'declaration of experience and competency form', which would be completed by new consultant radiologists. The form asked the individual to outline what ultrasound scans they were experienced and competent to complete.
- All staff files we reviewed contained evidence of disclosure and barring service (DBS) checks. This included the date of the check and whether the check had identified any past criminal history. DBS checks help employers make safer recruitment decisions and prevent unsuitable people from working with vulnerable groups.
- As part of our inspection, we also received the personnel files for the five clinic assistants. We found they all contained evidence of a recruitment and selection interview, employment history, their employment contract, training records and two satisfactory references.
- The service manager was responsible for appraising the clinic assistants. Appraisals were completed on an annual basis and once completed, were stored in staff files. Information provided by the service showed there was a 100% appraisal compliance rate.
- Each member of staff completed a local induction, which included mandatory and role-specific training. Staff told us they had received a good induction. New staff also received a staff handbook, which contained information about health and safety, whistleblowing, and incident reporting.
- At the time of our inspection, all the clinic assistants had completed face-to-face chaperone training.

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Multidisciplinary working

- Staff of different disciplines and from different providers worked together as a team to benefit patients.
- Staff from the service worked closely with the GPs, receptionists, and the GP practice manager. Staff reported excellent working relationships with the practice and told us they felt “like one big family”. Examples were given where service staff were invited to the GP practice social events.
- Stakeholder feedback about staff from the service was also positive. The relationship that had been built with GP primary care services had meant that an effective service was now being offered to the patients who were referred for ultrasound scans.
- During our inspection of Elms Medical Practice, we observed positive examples of the consultant radiologist and the clinic assistant working well together. Their professional working relationship promoted a relaxed environment for patients and helped to put the patients at ease.
- One of the three STAHMIS Ltd directors worked as a GP at the practice where the ultrasound clinic was held. This meant that any concerns relating to the Elms Medical Practice or its staff were resolved in a timely manner.
- The service used an electronic patient information system. This programme promoted multidisciplinary (MDT) use of records. This meant they were accessible by many healthcare professionals and ensured the health care record for the patient followed a smooth transition through the care pathway and allowed for good care planning and delivery of care.
- Staff told us if they identified any findings, which required escalation to another health provider, staff would immediately communicate with the patient’s GP through the instant messenger option on the electronic patient information system or via telephone. The scan report would also be sent to the referring GP immediately after the patient’s appointment.

Seven-day services

- As the service was not an acute service, it did not operate seven days a week. Clinics at the Elms Medical Practice were held on a Monday morning and all-day Thursday and Friday. If these clinic times were not suitable for patients, they could access different appointment times at the clinics held in St. Albans and London Colney.
- Additional clinics were provided on a Saturday on an ad hoc basis to compensate for cancelled appointments or when the service experienced increased activity.

Health promotion

- Staff could access health promotion literature available within the GP practice, if requested.

Consent and Mental Capacity Act

- All staff were aware of the importance for gaining consent from patients before conducting any procedures.
- There were processes to ensure patients consented to procedures. The patient’s verbal consent was sought on the day of the procedure and documented on the electronic patient information system. This was a mandatory field for all ultrasound scans. We saw that staff gained patients’ informed consent in the appointments we observed and the patient records we reviewed.
- Patients 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.
- Staff understood the principle of assessing mental capacity and best interest decisions but they had not had to apply this knowledge.
- Mental Capacity Act (MCA) and Deprivation of Liberty Safeguards (DoLS) training was completed by the consultant radiologists as part of their mandatory training at their substantive employer. At the time of our inspection, 100% of the consultant radiologists had completed this training.
- The service had a mental capacity and consent policy in place, which provided staff with information about

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patients who may lack capacity and guidance on what action they should take. It was the responsibility of the referring GP to inform the service about whether there were any concerns about a patient's mental capacity.

- The consultant radiologists were aware of 'Gillick' competencies for patients under the age of 18. To be Gillick competent, a young person (aged 16 or 17) can consent to their own treatments if they are believed to have enough intelligence, competence and understanding to fully appreciate what is involved in their procedure.

Are diagnostic imaging services caring?

Good 

We have not previously inspected this service. We rated caring as **good**.

Compassionate care

- All staff we spoke with were very passionate about their roles and were dedicated to making sure patients received patient-centred care. We observed staff treating and assisting patients in a compassionate manner.
- During our inspection of the Elms Medical Practice, we spoke with three patients about various aspects of their care. Without exception, feedback was consistently positive about the kindness and care they received from staff. One patient described staff as "really friendly and caring". Another patient told us the care they received was "faultless" and that it was "the most positive scan experience I have ever had".
- We observed staff introducing themselves to patients at the start of the appointments, and the patients we spoke with confirmed this.
- Staff respected patients' privacy and dignity. For example, the clinic room was locked when ultrasound scans were being undertaken, and patients were provided with a paper sheet to cover themselves during intimate scans. Patients we spoke with also confirmed staff respected their privacy and dignity. One patient told us that staff drew the curtains when they were getting changed for their scan.

- The service obtained patient feedback through an annual patient satisfaction survey. The survey allowed patients to give their feedback and provide a rating of their overall experience. In the January 2018 survey:
 - 17 patients rated their experience as 'excellent'.
 - 18 patients rated their experience as 'very good'.
 - Five patients rated their experience as 'good'.
 - One patient rated their experience as 'fair'.
- The service received three written compliments from July 2017 to July 2018.

Emotional support

- Staff were aware that patients attending the service were often feeling nervous and anxious so provided additional reassurance and support to these patients. The clinic assistants acted as chaperones during intimate ultrasound scans to ensure patients received emotional support.
- Staff understood the impact that a patient's care, treatment, or condition had on their wellbeing, both emotionally and socially.
- We observed staff providing kind, thoughtful, supportive and empathetic care.

Understanding and involvement of patients and those close to them

- Staff took the time to explain the procedure to the patient before and during the ultrasound scan. Staff adapted the language and terminology they used when discussing the procedure with the patient. The service provided ultrasound scans to a range of patients. Therefore, it was important for staff to use appropriate language, which the patient understood.
- We observed that staff also communicated to relatives and carers in a way they could also understand.
- Patients were provided with the opportunity to ask questions about their ultrasound scan and its findings. Feedback from patients also confirmed that they were informed about how they would receive the scan results.
- Staff recognised when patients and those close to them needed additional support to help them understand and be involved in their care and

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treatment, and enabled them to access this. For example, the service used a telephone translation service for patients who did not speak English as their first language.

- The service allowed a family member, friend, or carer to remain with the patient for their scan.

Are diagnostic imaging services responsive?

Good 

We have not previously inspected this service. We rated responsive as **good**.

Service delivery to meet the needs of local people

- STAHMIS Ltd was commissioned by the local clinical commissioning group (CCG) to provide consultant-led ultrasound scans. Services were provided from three GP surgeries across Hertfordshire, and meant people could access ultrasound scans within their local community without having to travel to an NHS acute hospital.
- Feedback from external stakeholders demonstrated the positive impact the service had on the local population. A GP commented, “it would be a tragedy to return to the old system”.
- The service offered a range of appointment times and days to meet the needs of the patients who used the service. Evening appointments had been trialled within the service; however, patient uptake was poor so these appointments were no longer offered. Patient feedback confirmed that patients were offered a choice of appointment and location, where possible.
- The CCG monitored STAHMIS Ltd’s progress in delivering their service against its contractual agreement via quarterly performance review meetings.
- STAHMIS Ltd had not renewed its contract with the CCG, which meant that by March 2019 the service would no longer provide diagnostic services. At the time of our inspection, the contract was out to procurement.

- Elms Medical Practice was located near established routes, with a bus stop and a train station a short distance away. Patients were also able to use free and accessible car parking.
- All appointments were confirmed two days prior to the patient’s appointment by letter or a text message reminder. This helped to reduce the number of patients who did not attend (DNA) their appointment.
- The GP practice had facilities for wheelchair users and breastfeeding, and provided privacy and dignity. There was sufficient space in the clinic room for individuals to accompany a patient, for example, carers, family, partners, as well as patients.

Meeting people’s individual needs

- The service took account of patients’ individual needs. The referral process meant patients’ individual needs were identified. We saw that on the referral form a box had been included for referrers to indicate whether the patient had any additional needs; such as mental health concerns, high body mass index (BMI), or a learning disability. If a patient with a learning disability was referred to the service, there was a mandatory box for the clinic assistants to complete to acknowledge they had seen this information.
- Staff told us they rarely had patients attend their clinics for an ultrasound who had complex needs. However, when they did, staff ensured the patient’s needs were met and facilitated their relatives or carers to accompany them during their scan. Appointment times would also be extended to ensure patients were not rushed.
- The service did not provide training to support clinic assistants to communicate and care for people living with dementia, learning difficulties or a mental health condition. The clinic assistants we spoke with during our inspection, told us additional training would be extremely beneficial for their role. Training records indicated that five of the seven consultant radiologists had received dementia training, which they had accessed through their substantive employer.
- Staff could access telephone interpreting services for patients whose first language was not English, when needed. Staff we spoke with knew how to access this, although none had needed to use it.

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- The GP surgery and ultrasound room was accessible to wheelchair users.
- The couches used for patients to lie on when having their scans, could not accommodate bariatric patients (patients with a BMI of 40 or above) and there was no hoist available for immobile or non-weight bearing patients. Patients requiring bariatric services or a hoist were referred to alternative providers.
- Patient feedback gathered during our inspection of the Elms Medical Practice, indicated that some patients felt they did not receive adequate information about what their scan would involve prior to their appointment. Following our inspection, the service adapted their text message appointment reminder to include a link to the 'About your scan' page on their website.
- To improve their waiting time performance, the service had:
 - Recruited an additional clinic assistant to help reduce delays in getting appointments booked.
 - Increased the overall clinic provision.
 - Increased their frequency of contact to patients who failed to respond to phone calls and letters regarding their appointment.
- From August 2017 to August 2018, 260 appointments were cancelled across all three of the STAHMIS locations. All were cancelled due to non-clinical reasons, such as family bereavement or severe weather. The service responded by offering patients the next available appointment and added in additional clinics at the weekends to compensate.

Access and flow

- People could access the service when they needed it. Referrals were prioritised by clinical urgency and based on the agreed commissioning pathway. Waiting times from referral to receiving the ultrasound scan were in line with good practice.
- The referring GP indicated whether the patient required an urgent or routine ultrasound scan on their referral from. The clinic assistants triaged patients accordingly, and extended clinics so patients accessed the service in a timely manner, where possible. Staff ensured urgent appointment slots were available in each clinic to accommodate patients who needed to be seen quickly.
- Service-level performance data was collected, audited, and reported to the CCG four times a year. The service recorded the times taken from referral to undertaking the ultrasound scan for all three locations. The target set by the CCG was 10 working days for urgent referrals, and 20 working days for routine referrals. Data from January to September 2018, showed that 94% of urgent referrals were completed within 10 working days and 73% of routine referrals were seen within 20 working days. Patient feedback during our inspection confirmed patients had received their appointment in a timely manner. Similarly, results from the 2018 patient survey indicated that most of the patients were seen within two weeks (33 out of 41 patients).
- Senior managers told us that the number of ultrasound scans performed each year had remained stable. From March to August 2018, the Elms Medical Practice completed 2,246 ultrasound scans.
- There was a process in place to ensure patients who did not attend appointments were followed up. At the end of each clinic, the clinic assistant telephoned the patients who missed their ultrasound scan and offered them a new appointment. If a patient did not attend two consecutive appointments, a letter was sent to the patient informing them they had 14 days to re-book their appointment. After this time, the referral was sent back to the patient's GP. From October 2017 to September 2018, 323 patients did not attend their appointment with STAHMIS Ltd.
- To help reduce DNA rates, the service had set up a text message reminder service for patients. A text message was sent to the patient 48 hours prior to their appointment and reminded the patient of the date, time, and location of their appointment. Staff told us that since the introduction of the text reminder service, the number of DNAs had reduced.
- Patient feedback gathered during our inspection, confirmed that patients were kept informed about appointment delays and received an apology from staff for their delay. During our inspection, we observed that the clinic at the Elms Medical Practice

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generally ran on time. Results from the patient satisfaction survey completed in January 2018, indicated that most patients were seen within five minutes of their appointment time:

- 14 patients reported that they were seen immediately.
- 11 patients reported that they were seen within five minutes of arrival.
- 14 patients reported that they were seen within 10 minutes of arrival.
- Two patients reported that they were seen within 20 minutes of arrival.
- Clinic assistants booked 'catch-up clinic slots' when they anticipated procedures may take longer than usual to help prevent clinic delays. For example, catch-up slots were booked into clinics that included children, less mobile patients, or pelvic scans.

Learning from complaints and concerns

- The service treated concerns and complaints seriously, investigated them and shared any learning with staff.
- STAHMIS Ltd had a complaints policy in place, which was last reviewed in August 2018, and outlined the process for recording and investigating complaints. The service manager was responsible for investigating and responding to complaints. The staff we spoke with were aware of the complaints process and policy and where possible, they tried to resolve informal complaints immediately before they developed into more significant complaints.
- The complaints policy stated that all complaints would be acknowledged in writing within three working days of receipt of the complaint. The complainant would then receive the full complaint response within 20 working days, unless a different timescale was agreed with the complainant.
- From July 2017 to July 2018, STAHMIS Ltd received six complaints. All six complainants received an acknowledgement letter and the full complaint response within the timeframes set out in the service's complaint policy.

- We reviewed the complaint responses, and found that all the complaints were treated with the same level of importance. We saw that action was taken in response to the complaints received to help improve patient experience and care provision. For example, following a complaint regarding the role of the chaperone in appointments, the clinic assistants received additional training and were reminded about the importance of supporting patients throughout their entire scan. STAHMIS Ltd also shared this feedback with their GP practices.
- Complaints and their outcomes were discussed and shared with all staff as part of the clinical governance and team meetings. The meeting minutes we reviewed corroborated this. Complaints were also a standing agenda item for discussion at the director meetings.
- Patient information leaflets, explaining how patients and those close to them could raise concerns or complaints, were displayed in the clinic room. Details of how to make a complaint was also published on the STAHMIS Ltd website. Despite this, none of the patients we spoke with were aware of how to raise a complaint. However, they all told us they felt comfortable discussing any concerns they had directly with the staff in the clinic.

Are diagnostic imaging services well-led?

Requires improvement 

We have not previously inspected this service. We rated well-led as **requires improvement**.

Leadership

- At the time of our inspection, the service did not have a registered manager in post, and had not had one since September 2017. However, a few weeks prior to our inspection, a new STAHMIS manager had been appointed and this individual was in the process of applying to become the registered manager.
- Despite only being in a post a few weeks, the new manager had a good awareness of the service's

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performance, limitations, and the challenges it faced, and these were all documented on the service's risk register. They were also aware of the actions needed to address those challenges.

- The previous STAHMIS manager continued to support and co-lead the organisation in their role as the service manager. The service manager was primarily responsible for the day-to-day running of the service and line managed the clinic assistants. An assistant manager had recently been appointed to provide additional support to the service. In addition, temporary support had been sourced for a couple of months until the assistant manager had completed their induction.
- Staff knew the management arrangements and told us they felt well supported. They said the managers were friendly and approachable, and they felt confident to discuss any concerns they had with them.
- Staff felt they had been kept well informed about the uncertain future of STAHMIS Ltd, and reported that the service manager was open and honest about the situation.
- There were two STAHMIS Ltd directors. From observation and discussions with staff, their involvement in the day-to-day running of STAHMIS Ltd was minimal. However, they were responsible for managing the service's finance and contractual arrangements with the local clinical commissioning group (CCG) and GP surgeries.
- The directors held quarterly meetings to discuss the service's performance, waiting times and patient feedback. However, from our review of meeting minutes, we found that the director meetings were not held consistently.

Vision and strategy

- STAHMIS Ltd had a mission for what it wanted to achieve. The mission was to "provide a high-quality service with the best possible patient experience... which meet and exceed the requirements and expectations of the GP surgeries and patients". There were also mission aims, which identified what the service needed to do to achieve their vision.

- Whilst the staff we spoke with were unable to fully articulate the vision, it was evident they always worked within the ethos of it. Staff told us they "aimed to achieve a gold standard service".
- At the time of our inspection, the service did not have a formal strategy in place. This was because the STAHMIS manager was awaiting confirmation about who had successfully secured the new contract with the CCG. Once the service had received this information, a new strategy, which focussed on the safe and smooth handover of services to the new provider, would be implemented.

Culture

- The managers promoted a positive culture that supported and valued staff, and this was evident during our inspection. We spoke with seven members of staff who all spoke positively about the culture of the service. There was a sense of ownership and pride in the service provided.
- Staff told us that STAHMIS Ltd was a good company to work for and they felt proud of the service they provided for patients.
- The service had an open and honest culture. Any incidents or complaints raised would have an open and honest 'no blame' approach to the investigation. However, in circumstances where errors had been made, apologies would always be offered to the patients 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. Negative feedback from patients about the service they had received was immediately discussed with the individual involved to ensure it was not repeated.
- During and after our inspection, we informed the STAHMIS 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.

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Governance

- One of the STAHMIS directors had overall responsibility for clinical governance and quality monitoring. However, their involvement in the service was minimal, and meant we were not assured there was a robust governance framework in place.
- According to the service's clinical governance and discrepancy meeting policy, clinical governance meetings should have been held every two months. However, meeting minutes indicated that they were not held this frequently. We reviewed the meeting minutes for the last three clinical governance meetings, which were held in June 2017, December 2017, and June 2018.
- The clinical governance meeting minutes demonstrated that complaints, incidents, and service changes were reviewed. However, there was no evidence that changes to local policies, national guidance or patient safety alerts were discussed.
- There was not a robust process in place for reviewing, managing, and granting practising privileges. There was no formal arrangement in place to ensure STAHMIS Ltd was informed of any performance problems or other concerns relating to a consultant's practice. Following our inspection, the service implemented a 'Practising Privileges Agreement', which formally specified the ongoing obligations between the consultant radiologists and STAHMIS Ltd. We were told that the management of practising privileges would be monitored and reviewed through the newly introduced medical advisory committee (MAC). The MAC would consist of the service directors, the clinical lead and the STAHMIS manager.
- We found that the consultant personnel files did not contain evidence of their appraisals, which had been completed by their substantive employer. This meant we could not be assured that STAHMIS Ltd had full oversight of the competencies, skills and capabilities of staff working for their service. We raised this as a concern to senior managers during our inspection, who told us they would review this process. Following our inspection, the service ensured they had a copy of the consultants' most recent appraisals in their staff files. They also included this as an annual requirement on their staff file checklist.

- All staff given practising privileges had professional indemnity insurance in place.
- Working arrangements with the local CCG and GP surgeries were managed well. There were service level agreements and a contract between the service, GP practices and the CCG. The service attended quarterly performance and review meetings with the CCG to discuss the service provided.

Managing risks, issues and performance

- The service had processes to identify, understand, monitor, and address current and future risks.
- The service had a risk register in place to identify and manage risks to the service. The risk register comprised of five open risks, and included a description of each risk, alongside mitigating actions. An assessment of the likelihood of the risk materialising, its possible impact and the risk owner were also included.
- We were told that risks were reviewed at the director meetings. However, minutes from the meeting held in June 2018, indicated that risks and their mitigating actions had not been discussed or reviewed at this meeting. Therefore, we could not be assured the service was taking timely and appropriate action to address the risks within the service. Following our inspection feedback, the service included reviewing the risk register as a standing agenda item at their directors meeting, alongside finance, quality assurance and contract management.
- All staff we spoke with could clearly articulate the main risks to the service and what was being done to address them.
- The service's risk register contained a risk relating to the service performing unnecessary ultrasound scans. This risk had been graded as 'moderate' by the service. We saw that actions had been taken to mitigate this risk, including implementing the iTriage system for the GPs. Staff told us that since the implementation of the triage tool, they rarely received inappropriate referrals. From December 2017 to September 2018, STAHMIS Ltd received 34 inappropriate referrals, which predominately related to GPs requesting breast ultrasound scans.

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- Performance was monitored using key performance indicators (KPIs), which were set by the commissioning CCG and regularly reviewed at the joint performance review meetings. We saw that patients were generally booked within the agreed timeframe set by the CCG; for urgent referrals the patient should be seen within 10 working days and within 20 days for routine referrals. Data from January to September 2018, showed that 94% of urgent referrals were completed within 10 working days, and 73% of routine referrals were seen within 20 working days. The service was acting to improve their waiting time performance.
- STAHMIS Ltd also monitored the number of cancelled appointments, inappropriate referrals and patients who did not attend their appointments.
- There was not a comprehensive assurance system in place to monitor consultant performance. The service was unable to provide us with evidence of their peer review audits, which they told us were completed as part of the clinical governance meetings at the local NHS trust. Therefore, we could not confirm whether the peer review audits were being undertaken, as recommended by the British Medical Ultrasound Society. We were concerned that potential learning opportunities would be missed. Following our inspection, senior managers told us they had discussed our concern with the clinical lead, who was responsible for ensuring the audits were completed. The clinical lead had agreed to begin formally documenting this work.
- Findings from audits were not widely shared within the service. We reviewed the last three clinical governance meetings, and did not see evidence that audit findings and recommendations were discussed or reviewed. This meant we could not be assured that learning from audits were identified, taken forward and implemented.
- A business continuity plan was in place detailing the action the provider would take in the event of a major incident and also covered business continuity in the event of adverse weather and information technology disruption.
- 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 patient'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 the regulations.
- Information governance training formed part of the mandatory training programme for the service and at the time of our inspection, all the clinic assistants had completed this training. Staff we spoke with understood their responsibilities regarding information management.
- Electronic patient records were accessed easily but were kept secure with staff locking the computer terminals when not in use. Printed clinic lists were also turned over during patient appointments to prevent information breaches.

Engagement

- STAHMIS Ltd engaged well with patients, staff and local organisations to plan and manage appropriate services, and collaborated with partner organisations effectively.
- The service ran an annual patient survey for patients to give their feedback about their experience. The results from the latest survey, completed in January 2018, was overwhelmingly positive with 98% of patients rating their overall experience as 'excellent', 'very good' or 'good'.
- There was a website for members of the public to use. This held information regarding the types of scans offered and what preparation was required for each type. There was also information about how patients could provide feedback regarding their experience.
- We saw that patient feedback was taken seriously and used to improve the service. For example, following patient feedback, the service ensured water was readily available for patients in their clinic locations.
- Results from the patient survey and patient complaints were discussed with the team during

Managing information

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clinical governance and team meetings. The clinic assistants had received additional training in customer service to patients were provided with the best possible experience during their appointments.

- Staff had formulated a positive relationship with external stakeholders and partners. The service regularly asked local GPs to provide feedback about their experience of the service. We reviewed a sample of GP feedback, and found it was all extremely positive. One GP commented, “the STAHMIS service has been invaluable and the prompt access to scans has greatly benefitted patient care and the further management of patients”. Another GP referred to the service as “absolutely fantastic” and a “cornerstone of modern medical care”.
- Clinic assistant team meetings were held quarterly. However, due to staff availability, they were not always held this frequently. Despite this, staff told us they felt actively engaged in service planning and development, and were kept well informed about the potential closure of the service. We reviewed the last three team meeting minutes held in May 2017, October 2017, and February 2018, and saw that changes to service provision and documentation, complaints, incidents, and patient feedback were discussed.

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 senior management team took immediate and effective actions to address some of the concerns we raised during the inspection.
- GP feedback indicated that STAHMIS Ltd regularly improved the timeliness of patients’ diagnoses and subsequent treatments. For example, two patients were referred to the service for an ultrasound scan of a suspicious lump. Unfortunately, their scans indicated the lumps were cancerous. The referring GP was informed of the results immediately, and the patients were referred for treatment. The referring GP commented, “this may be lifesaving for them”.
- In addition, a patient was urgently referred to the service with left-sided abdominal pain. The patient was seen by a consultant radiologist within two days of the referral, and was diagnosed with colon cancer. The referring GP commented, “this is not the first cancer I have picked up early using STAHMIS scans. I can think of at least three in the last six to nine months”.

Outstanding practice and areas for improvement

Areas for improvement

Action the provider **MUST** take to improve

- The provider must ensure there is a robust process for reviewing, managing and granting practising privileges.
- The provider must ensure all their staff files are up-to-date and complete, including evidence of staff appraisals.
- The provider must ensure that peer review audits are completed and formally documented, and the results are disseminated to staff at the local clinical governance and director meetings.
- The provider must ensure risks to their service are regularly reviewed, and these discussions are documented within the appropriate meeting minutes.

Action the provider **SHOULD** take to improve

- The provider should ensure there is a process in place to update staff about changes to local or national guidance and legislation.
- The provider should ensure staff meetings, such as the clinical governance and director meetings, take place regularly.
- The provider should carry out regular hand hygiene audits to monitor and improve infection prevention and control practices.
- The provider should consider providing training for staff on how to communicate and care for patients living with dementia, learning difficulties and mental ill health.

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>1) systems and processes must be established and operated effectively to ensure compliance with this part.</p> <p>(2) without limiting paragraph (1), such systems or processes must enable the registered person, in particular, to-</p> <p>(a) assess, monitor and improve the quality and safety of the service provided in the carrying on the regulated activity (Including the quality of the experience of the service users in receiving those services);</p> <p>(b) assess, monitor and mitigate the risks relating to the health, safety and welfare of service users and others who may be at risk which arise from the carrying on of the regulated activity.</p> <ul style="list-style-type: none">• The service did not have a robust process for reviewing, managing and granting practising privileges.• The consultant staff files did not contain evidence of their appraisals and not all of the files had two references recorded to provide evidence that they were of good character and suitable for their role.• There was no evidence that peer review audits of the ultrasound images and reports were undertaken, as recommended by the British Medical Ultrasound Society (BMUS).• There was no evidence that risks to the service and their mitigating actions, were discussed or reviewed.