Community Imaging Services Limited

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?	Good

Summary of findings

Letter from the Chief Inspector of Hospitals

Community Imaging Services Limited is an independent ultrasound service . The service registered with the CQC in April 2018 and began delivering services in October 2018.

The service has never been previously inspected.

We inspected this service using our comprehensive inspection methodology. We carried out an announced inspection on 4 April 2019.

We rated the service as good overall.

Our key findings were as follows:

- Managers in the service monitored staff compliance with mandatory training in key skills and made sure everyone had completed training specific to their roles to support the delivery of safe care.
- Staff understood safeguarding processes and were confident to escalate concerns.
- The maintenance and use of equipment kept people safe.
- The service considered and took actions to lessen risks to patients.
- The service had enough staff with the right qualifications, skills, and training to provide the right care and treatment. Employment and qualification checks were carried out on all staff.
- Peoples' individual care records were completed and managed in a way that kept people safe.
- The service provided care and treatment that was based on national guidance and evidence of its effectiveness.
- Throughout our inspection we saw that patients were treated with compassion, kindness, dignity, and respect.
- The service planned and delivered services in a way that met the needs of patients. The importance of flexibility, choice and continuity of care was reflected in the service provided.
- The service took account of patient's individual needs.
- People could access the service when they needed it. Waiting times from referral to treatment were in line with good practice.
- Leaders of the service had the right skills and experience to run the service.
- The managers across the service promoted a positive culture that supported and valued staff, creating a sense of common purpose based on shared values.
- The service managed and used information to support its activities, using secure electronic systems with security safeguards.

However, there were areas where the service needs to make improvements:

- All staff did not consistently follow hand hygiene requirements in line with the service's infection prevention control policy.
- Patient consent for procedures was not consistently documented by all staff, line with best practice guidance.
- There was information contained in the accident and incident reporting, and risk management policies and procedures, which provided conflicting information to staff.

Summary of findings

- There was not a formalised process in place to minute all meetings, including staff meetings within the service, and meetings between the service and the gynaecology 'one-stop shop' provider.
- There was limited engagement activity within the service. Minimal patient and staff feedback was gathered, in order to inform service improvements.

Following this inspection, we told the provider that it should make improvements, even though a regulation had not been breached, to help the service improve. Details are at the end of the report.

Amanda Stanford
Deputy Chief Inspector of Hospitals

Summary of findings

Our judgements about each of the main services

Service	Rating	Summary of each main service
Diagnostic imaging	Good	Overall, the care provided by the service was safe, effective, caring, responsive and well led. Patients were happy with the care they received and we found the service to be caring and compassionate. Staff were well trained and supported and worked according to agreed national guidance to ensure patients received the most appropriate care. There were sufficient staff, with appropriate skills and expertise to manage the service. Staff had a clear understanding of safeguarding processes and were confident to escalate concerns. Scans were reported on during the procedure and were available immediately to consultants working in the gynaecology 'one-stop shop' service.

Summary of findings

Contents

Good

Community Imaging Services Ltd

Services we looked at
Diagnostic imaging

Summary of this inspection

Background to Community Imaging Services Ltd

Community Imaging Services Limited (CISL) is an independent provider of ultrasound service They provide gynaecological scans as part of a gynaecology 'one-stop shop' service for females aged seventeen and over. They work in partnership with a local provider who hold the contracts with the Clinical Commissioning Groups (CCGs). CISL have a subcontract arrangement with the provider who holds the CCG contract. CISL provide the ultrasound scan element of the service only. They deliver NHS activity only. An ultrasound is a diagnostic procedure that uses high frequency sound waves to capture live images from inside of the body.

CISL has a registered provider address at London Colney Medical Centre. This is a GP practice located within the St Albans area which primarily serves the communities of St Albans and the surrounding areas. This is the main site for the service delivery and was the site visited during the inspection. Additionally, there are three further sites which are at Park End Surgery Watford, and Longrove Surgery and Oak Lodge Medical Centre in Barnet. The CISL service accesses ultrasound scanning rooms at the four sites and shares facilities which include administrative and bookings staff, reception staff, waiting room facilities and one ultrasound scanning room at each site. Ultrasound scanning rooms are available on the ground floor and on the first floor, where there are lifts to access these rooms. Disabled toilet facilities are available at all sites. There is car parking available at all sites, including some designated disabled parking bays.

Our inspection team

The team that inspected the service comprised of a CQC lead inspector and a second inspector. The inspection team was overseen by Bernadette Hanney, Head of Hospital Inspection.

Information about Community Imaging Services Ltd

The service provides diagnostic imaging and is registered to provide the following regulated activities:

- Diagnostic and screening procedures.

During the inspection, we visited one ultrasound scanning room at the main site of service delivery. We spoke with four staff including; a sonographer, the registered manager, and two directors of the service. We spoke with four patients and observed four episodes of patient care delivery. During our inspection, we reviewed ten ultrasound scan reports. We reviewed policies, training records and audit results.

There were no special reviews or investigations of the service ongoing by the CQC at any time during the 12 months before this inspection. The service has not been inspected previously.

Activity (April 2018 to March 2019)

The service undertook 1,845 scans during the year. All patients were NHS-funded.

Track record on safety

- No Never events, serious injuries or deaths
- One clinical incident reported with no harm.
- No complaints were reported, however, the clinical incident which was reported was a result of a verbal concern raised by a patient.

Services provided at the service under service level agreement:

- Cleaning services
- Maintenance of medical equipment

Summary of this inspection

- Administrative and support staffing provisions
- Appointment booking processes

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	Good	Good
Overall	Good	N/A	Good	Good	Good	Good

Good

Diagnostic imaging

Safe	Good
Effective	
Caring	Good
Responsive	Good
Well-led	Good

Are diagnostic imaging services safe?

Good

Mandatory training

- **The service monitored staff compliance with mandatory training in key skills and made sure everyone completed it.**
- There were three sonographers who were locum staff and were not directly employed by the service. The sonographers and the director (who was a consultant radiologist) were employed in substantive posts in the NHS. Staff were responsible for completing the mandatory training with their substantive employer. The deputy manager was responsible for reviewing compliance and had a process to monitor this. There was a list of mandatory training topics to be completed. These included basic life support, manual handling, infection prevention and control, safeguarding and health and safety. The deputy manager informed staff of when they were due an update, and asked them to provide evidence when training updates had been completed.
- The service reported that staff were up-to-date with training requirements. At the time of our inspection there was 91% overall compliance with staff completion of mandatory training topics.

Safeguarding

- Staff understood how to protect patients from abuse and the service worked well with other agencies to do so. Staff had training on how to recognise and report abuse and they knew how to apply it.
- There were systems, processes and practices to keep both adults and children safe from abuse. The safeguarding policy was in date and was due for review in June 2020. It described the definition of abuse and neglect, who might be at risk, general indicators, and what actions to take if staff suspected abuse. The policy was easily accessible in a service information folder and included contact details for safeguarding leads, the local authority, and emergency out of hours services.
- Staff we spoke with had a clear understanding about safeguarding, knew what the signs of abuse might be, and where to access support if they had any concerns. They were confident about how to escalate concerns to the safeguarding lead. There had been no safeguarding referrals since the company became operational in October 2018.
- Community Imaging Services Limited had an identified lead for safeguarding, which was the registered manager who was level three safeguarding adults trained in line with national guidance. The consultant radiologist, who was a director of the service, was level three safeguarding children trained.
- All clinical staff had completed level two in safeguarding adults and children. This was in line with the Safeguarding children and young people: roles and competencies for health care staff Intercollegiate document.
- Staff had a Disclosure and Barring Service (DBS) check at the correct level for their role. This was to help detect and prevent unsuitable people from working

with vulnerable groups, including children. For example, the sonographer had an enhanced disclosure level check; as stipulated in and required by the service's safeguarding policy.

- Administrative, reception and support staff were provided through the subcontract arrangement with the local provider for the gynaecology 'one-stop shop' service.
- The female genital mutilation (FGM) policy was part of the safeguarding policy and was in line with the Department of Health female genital mutilation and safeguarding guidance for professionals (2016). Staff were clear about how they escalated any concerns they had. FGM was part of the safeguarding mandatory training programme.

Cleanliness, infection control and hygiene

- **The service generally controlled infection risk well. Staff kept themselves, equipment and the premises clean. They mostly used control measures to prevent the spread of infection however, the hand hygiene policy was not adhered to at all times.**
- One sonographer we observed did not decontaminate their hands prior to performing patient procedures, however, they decontaminated their hands following each patient procedure. This was not in line with the hand hygiene guidance in the infection prevention control policy, which stated that staff should decontaminate their hands both before and after procedures.
- We observed the sonographer clean the ultrasound probe and cable, with antiseptic wipes after it was used on each patient. As all scans performed were trans-vaginal scans (where the probe is inserted into the outer vagina), disposable latex-free sheaths were placed over the probe and replaced for each patient. Cleaning of the probe, and staff hand decontamination were not carried out in full view of the patient at the beginning and end of the examination, in line with good practice (The Society and College of Radiographers / The British Medical Ultrasound Society Guidelines for Professional Ultrasound Practice. Revision 3. December 2018). It is good practice (as for any examination) to ensure that, when possible, hand washing and equipment cleaning are carried out in full view of the patient at the beginning and end of the examination to reassure him or her that effective infection control procedures are being applied.
- The waiting room and clinical areas used by Community Imaging Services Limited (CISL) were the responsibility of the GP practice in which they were based. The gynaecology 'one-stop shop' service, which CISL subcontracted to, had an agreement with the GP practice as part of their contract for the cleaning of the clinical areas used. General cleaning of the premises was undertaken daily and, during our inspection, clinical areas appeared visibly clean and tidy.
- Furniture in waiting areas and in clinic rooms was wipeable so could be decontaminated easily. Clinical staff ensured equipment was kept clean between patients and at the end of each clinic. A paper towel covering the couch was replaced between each patient and the couch and ultrasound machine were wiped down with antiseptic wipes at the end of each treatment session. There was a daily cleaning schedule for the clinical equipment, which we observed had been completed daily.
- The service reported that 100% of staff had completed infection control training. There was an infection control policy that was up to date and in line with the Department of Health (2009) The Health and Social Care Act 2008: Code of Practice for health and adult social care on the prevention and control of infectious and related guidance.
- The consultant radiologist conducted an infection control audit once a year. The last audit was undertaken in March 2019 and, although the audit was not scored, the service demonstrated overall compliance against an inspection checklist. This reviewed the environment cleanliness, waste management processes, and hand hygiene facilities.
- The infection control audit did not include observation of hand hygiene practices of individual staff members. As hand hygiene was not regularly monitored, the service was unable to ensure the spread of infection was minimised. We fed this back to the consultant radiologist (service director) who told

us they planned to review this. Following our inspection a hand hygiene audit of the three sonographer staff was completed which showed 100% compliance with the audit standards.

- We observed throughout our inspection that staff were compliant with best practice regarding being bare below the elbow during clinical activities.
- Hand gel and clinical hand wash basins with elbow operated taps were available in the scanning room. There was a hand hygiene poster above the sink prompting staff to follow effective hand washing techniques.
- Staff told us that if there was a patient with a known infectious illness, they would schedule the appointment for the end of the session. In addition, all equipment would be cleaned with disinfectant wipes after the patient had been seen.
- Domestic and clinical waste was handled and disposed of in a way that kept people safe. There were separate clinical and non-clinical waste disposal bins with labelled coloured bags to ensure that staff used the correct system to handle and sort different types of waste.
- There was a cupboard in the scanning room which was labelled COSHH (control of substances hazardous to health) and contained a spill kit for the safe clean-up and disposal of bodily fluids such as blood, vomit, and urine.
- Personal protective equipment, including latex free gloves, was readily available in the clinical area and we observed staff using it.

Environment and equipment

- **The service had suitable premises and equipment and looked after them well.**
- Community Imaging Services Limited (CISL) used premises and equipment within four separate GP surgeries across the St Albans area. The service accessed one ultrasound scanning room at each site and shared the facilities, such as reception and waiting areas. The maintenance of the premises and equipment, except a mobile ultrasound machine, were the responsibility of the GP surgery leads or gynaecology 'one-stop shop' service.
- Ultrasound equipment had a yearly service carried out by manufacturers' engineers. There were two fixed ultrasound machines and one portable machine used by CISL across the four sites of service delivery. The fixed equipment did not belong to CISL, but was the property and responsibility of the gynaecology 'one-stop shop' service which CISL subcontracted to. CISL did not maintain a service record log however, as there were only three items of equipment, the deputy manager checked the dated stickers on the machines. The service company also sent a reminder of when the equipment was due for service. The ultrasound machine at the main site was within date for testing. CISL owned a portable ultrasound machine which was used at two of the sites and the consultant radiologist provided an up-to-date service history for the machine. Quality assurance checks were conducted annually by the service company and the machines had an automated quality control system to highlight if there were any problems. If problems were found, the service company was contacted for the machine to be checked by qualified personnel.
- There were processes for managing faulty equipment. Staff checked the equipment before every clinic and if any fault was found the clinical lead was informed. The lead was responsible for organising any repair. Whilst faulty equipment was out of use during repair, the portable ultrasound machine was used or a temporary machine was rented. If alternative equipment was not available for any reason, all patients would be cancelled and rebooked for the next available appointment.
- Servicing and maintenance of premises and all equipment was the responsibility of the gynaecology 'one-stop shop' service which CISL subcontracted to. In the scanning room, we saw that the premises and equipment were in a good state of repair and were fit for purpose.
- The site we inspected used one clinic room which housed a fixed ultrasound scanning machine. The scanning room was spacious and had good lighting which dimmed to allow ultrasound scans to be clearly seen.
- We saw clinic store cupboards stocked with equipment needed for ultrasound such as gels,

ultrasound probes and sheath covers. All gels and sheath covers we checked were within their expiry date. Staff had access to all the equipment and supplies they needed to provide the service.

- The service had access to emergency equipment within the GP practice which included emergency drugs, oxygen and a defibrillator. The equipment was stored in a cupboard within one of the other clinic rooms (not the scanning room). The gynaecology 'one-stop shop' service staff were responsible for the emergency equipment. Records indicated emergency equipment had been checked weekly by qualified staff and was ready for use in an emergency.
- Fire safety training formed part of the mandatory training programme. Mandatory training records showed 100% of staff were compliant with fire training through their NHS employers. In addition, staff received a local building induction when starting work with the service, which included information about fire safety. We saw evidence that fire alarms were tested once a week. We observed fire notices indicating the nearest exit and the assembly point. There were fire extinguishers in the corridor which were easily accessible and were found to be within their expiry date for service.

Assessing and responding to patient risk

- **The service had appropriate arrangements in place to assess and manage risks to women.**
- Patient referrals were screened against set criteria. GPs were given the criteria to follow when requesting a patient to be scanned however, the gynaecology 'one-stop shop' service staff screened all referrals before accepting. Patients suspected to have a malignancy, and those who weighed over 140kgs were referred to secondary care to ensure that the necessary equipment or patient pathways were available.
- The gynaecology 'one-stop shop' service who held the contract with the local commissioners was responsible for triaging referrals to the gynaecology 'one-stop shop' service. Consultant gynaecologists reviewed all new referrals daily to identify which patients required an ultrasound scan as part of the service. This included prioritising patients for urgency based on National Institute for Health and Care Excellence (NICE) guidelines (NG88) Heavy menstrual bleeding: assessment and management (March 2018). Patients referred by the GP as a two-week wait, urgent referral for suspected cancer were referred to the local acute hospital so that they could be seen without delay.
- The service had a robust process for reporting unexpected findings from ultrasound scans. Findings of concern were raised immediately with the consultant gynaecologist in the clinic. Staff told us there was always a consultant gynaecologist in the clinic to discuss scan findings with. This ensured that unexpected findings were promptly and properly investigated.
- Basic life support was included as part of mandatory training programme. The service reported that 100% of staff had completed the training. A sonographer was able to describe the process involved when managing a deteriorating patient and the situations which required immediate transfer to hospital such as a cardiac arrest, or sudden collapse. There was an emergency buzzer within the scanning room and an alert button on the electronic records system which enabled staff to seek urgent assistance in the event of a patient becoming unwell. There were consultants and general practitioner medical staff on site for advice when needed to decide whether transfer or admission to an acute hospital was required.
- There was a process to ensure the correct person and the right anatomy was scanned each time to minimise and prevent mistakes. We saw that staff followed the Society of Radiographers (SoR) "Pause and Check" guidelines. Pause and Check consists of a six-point check list to correctly identify the patient, as well as checking with the patient the site/side to be imaged.
- Patients were advised in the ultrasound appointment letter to inform the sonographer if they were allergic to latex, or lubricating jelly for example.

Staffing

- **The service had enough staff with the right qualifications, skills, training and experience to provide the right care and treatment.**
- The service had three sonographers who were employed on a locum contract basis. Clinical staff

worked on a part time basis to fulfil the service's requirement. Each sonographer worked specific days they had formally agreed with Community Imaging Services Limited (CISL). Staff were flexible with their working hours, and could extend their session hours if required.

- The sonographers had support of health care assistants (HCAs) who prepared the room between patients, typed up part of the report, and acted as chaperone. HCAs received chaperone training as part of their induction to the role. In addition, they shadowed more experienced members of staff in the role for a few sessions, before working in the role independently. HCAs, booking and reception staff were employed by the gynaecology 'one-stop shop' service which CISL subcontracted to.
- There were no current sonographer vacancies as the service did not employ staff on permanent contracts. The manager reported that locum staff in post were able to meet the current demands of the service and there was no need to source additional bank or agency staff. In the three months before the inspection, there were no episodes of sickness amongst sonographer staff which resulted in cancelled appointments, as bank staff and the consultant radiologist were available to cover sick leave.

Medical staffing

- The service had a clinical lead consultant radiologist who was one of the directors of the service. The radiologist worked at the main site one session a week to deliver clinical support and advice to the sonographer. In addition, the radiologist performed scans at one of the locations operating at a weekend, and was able to complete scans at other sites in the event of sonographer staff not being available. The radiologist was easy to contact when not on site by telephone or email during working hours. In the absence of the radiologist, staff were able to contact another consultant radiologist at the acute trust for advice. This was a goodwill arrangement as the sonographer staff worked at the same trust and hence had established working relationships.
- The registered manager was a registered GP although they did not have any direct clinical contact with the patients. They were available for general advice and support as required.
- No other medical staff were employed by the service.

Records

- **Peoples individual care records were completed and managed in a way that kept people safe. Records were clear, up-to-date, and easily accessible to staff providing ultrasound scans.**
- 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. The reports were written and stored on an electronic system. We reviewed ten sets of reports and found that all records were accurate, complete, and up-to-date. Each report included; patient identification, type of scan performed, date of the scan and of the report, clinical information, the name of the sonographer, presence of a chaperone, and a description of findings including a conclusion and recommendation.
- Report findings were dictated by sonographers to the health care assistant who typed the information into the electronic report template. The sonographer reviewed the report following the procedure and signed it off. The report was then immediately available, on the day of the procedure, to the consultant gynaecologist working in the 'one stop' clinic. Staff in the administrative team sent electronic copies of the scan report to the referring GP by secure email within one week of the appointment.
- Images were stored on an electronic portal and were available at all times to staff in the service. This included consultant gynaecologists working at the 'one stop' clinic, who could view copies of the report immediately following the scan. However, the portal was only accessible at the service delivery sites and not by other NHS providers.
- Patient images were stored on the ultrasound machine. Images were backed up to a hard disk which was stored in a locked safe in the manager's office. The service manager and three of the service directors had access to the safe.

- Patient records were accessible to staff who were authorised to access confidential data. The service manager was responsible for granting access, which was through a password protected login system.
- All patients who used the service were referred from GP practices within the local clinical commissioning groups. Referrals were received via a secure NHS email portal and processed by a bookings team which was part of the gynaecology 'one-stop shop' service.

Medicines

- Community Imaging Services Limited did not use any controlled drugs or medicines.

Incidents

- **Whilst staff understood their responsibilities to raise concerns, to record safety incidents, concerns and near misses, and to report them internally and externally, processes and procedures were not always clear.**
- There was an accident and incident reporting policy and procedure dated 13/12/2018. The policy did not however, provide explicit information on the accident/incident reporting process. The policy informed staff to report an accident/incident to the registered manager (RM) immediately. It did not state if this was by telephone or email, or who to escalate the accident/incident to in the absence of the RM. The policy contained specific information regarding the Reporting of Injuries, Diseases and Dangerous Occurrences Regulations requirements however, there was no information regarding what constituted other incidents such as equipment failure, manual handling incidents, or a safeguarding event, for example. One staff member we spoke with required prompting when asked what constituted an incident that required reporting. Furthermore, the timeframe for the completion of incident investigations was not set out.
- The accident and incident reporting forms were attached as appendices to the accident and incident reporting policy. Staff had access to the accident/incident policy and paper reporting forms that were filed in a service information folder with other key documents and polices. The folder was kept at the main site most of the time, but was taken with a sonographer when they used a portable ultrasound scanning machine at other locations. This meant staff always had access to policies and incident reporting forms.
- Patient safety was promoted through the sharing of incidents. One incident had been reported since the business became operational in October 2018. The incident concerned inaccurate information being contained in an imaging report. We observed that a thorough investigation and report had been completed by the director, in collaboration with the service lead from the gynaecology 'one-stop shop' service. Learning from the incident concerned adjusting the language used when sonographers reported on similar images. The learning was shared with the reporting sonographer in person, and with other staff via email/phone to ensure each person received the learning due to staff having different work days.
- Community Imaging Services Ltd did not report any 'never events' from October 2018 to March 2019. 'Never events' are serious incidents that are wholly preventable as guidance or safety recommendations that provide strong systemic protective barriers are available at a national level and should have been implemented by all healthcare providers.
- In accordance with the Serious Incident Framework 2015, the service did not report any serious incidents since the company opened in October 2018.
- Regulation 20 of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014 is a regulation introduced in November 2014. This regulation requires the organisation to be open and transparent 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 registered manager 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 directors were 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?

Evidence-based care and treatment

- **The service provided care and treatment based on national guidance and evidence of its effectiveness.**
- A sonographer referred to working within service policies and procedures. They told us that they followed guidelines from the British Medical Ultrasound Society (BMUS) and professional registration guidelines to guide their clinical practice. They explained there were treatment protocols to follow for different types of scans which were produced by the NHS trust where they worked. They applied these to their practice at Community Imaging Services limited (CISL) as there were no written protocols produced by the service.
- The provider ensured people had their needs assessed and their care planned and delivered in line with evidence-based guidance, standards and best practice. An audit plan included a monthly audit of image outcomes to ensure they met best practice guidance, such as the Society and College of Radiographers / the British Medical Ultrasound Society 'Guidelines for Professional Ultrasound Practice' Revision 3, December 2018. The consultant radiologist reviewed ten images and reports each month and graded them for image quality and report quality from one to five, where five indicated no concerns and one indicated serious omissions or misinterpretations that may result in serious morbidity or threat to life. The last three month's audit results showed 100% of image quality scores were graded as five. For report quality, 88% were graded as five and the remaining 12% as grade four. Grade four indicated a minor disagreement over the presentation of the report, for example typographical errors. We were assured from these audit findings that the service produced high quality images and reports.
- The audit plan included infection, prevention and control, patient feedback, and appointments (numbers of appointments booked, did not attend rates, and wait times in the clinic.) The provider did not have a clinical audit policy however, the director told us they would develop one to ensure there was a consistent approach to maintaining evidence-based care and treatment.
- We reviewed local policies and found that they were in date and version controlled however, most, but not all referenced guidance from professional organisations. For example, the accident and incident reporting policy and procedure dated December 2018 referred to the Reporting of Injuries, Diseases, and Dangerous Occurrences Regulations 1995; however, it did not reference the National Framework for Reporting and Learning from Serious Incidents requiring Investigation 2010. Most policies contained references to national guidance from the National Institute for Health and Care Excellence (NICE), and the Department of Health (DoH).

Nutrition and hydration

- Patients were advised in their appointment letter if they were required to have a full bladder prior to their ultrasound scan. Plastic cups were provided next to the sink in the main waiting room with a sign to inform patients that drinking water was available from the cold tap, if required.

Pain relief

- Community Imaging Services Ltd did not provide medication, however, staff checked throughout the scan if a patient was comfortable. Staff could ask for advice from a consultant in the gynaecology 'one-stop shop' service if a patient experienced pain that impacted on the procedure being undertaken.

Patient outcomes

- **The service monitored patient outcomes through a question in the gynaecology 'one-stop shop' service patient satisfaction survey.** This question

asked patients to rate the sonographer as 'excellent, good, fair or poor'. Data from January to March 2019 showed that 95% of patients rated sonographers as either excellent or good.

- In addition, they monitored waiting times during the clinic, activity (number of appointments booked) and "did not attend" data through audits. It was the responsibility of the main contract holder to report performance data to the clinical commissioning groups every month. However, a director of Community Imaging Services Limited met with the main contract holder of the gynaecology 'one-stop shop' service informally each week, and quarterly to review operational issues and service performance.

Competent staff

- **Staff had the right qualifications, skills, knowledge and experience to do their jobs.** Employment and qualification checks were carried out on all staff and copies were kept in a folder by the deputy manager.
- There was an induction programme for all new staff which included an orientation of the building and demonstration of the equipment used. In addition, staff had to complete a competency process which included observation of a clinical session by the consultant radiologist, before being signed off as competent to run a clinic independently. We saw that each staff member had a competency booklet completed and signed off by the consultant radiologist as evidence of achievement of competency.
- The clinical lead radiologist reviewed the quality of scan images and reports through a monthly audit, and any concerns were discussed with staff. The consultant radiologist told us that they would provide additional support and supervision for any sonographers where there were concerns about their images and reports. They told us that no sonographer had required this additional supervision to date.
- Sonography staff did not receive appraisals by managers in the service as they were not directly employed by the service. However, sonographers were required to provide evidence of having completed an appraisal in their NHS job role. The clinical lead radiologist also received an appraisal in their NHS job role and provided evidence of completion. The service manager completed an appraisal with NHS England.
- The service reported that 100% of sonographer staff had received an appraisal in their NHS job role in the last year.
- Sonographers do not have a protected title and are therefore not required to be registered with the Health and Care Professions Council (HCPC). However; radiographers that have an extended scope in sonography are required to be registered with the HCPC. Two of the three sonographers working for the service were extended scope radiographers and were registered with the HCPC. Registration meant that staff followed guidelines for professional practice which met the standards to ensure delivery of safe and effective services to patients. Clinical staff were required to complete continuous practice development (CPD) to meet their professional body requirements. Staff were required to renew their membership every two years and we saw that all clinical staff had successfully renewed their membership in March 2018. The third sonographer was a nurse who had completed additional training to become a sonographer, and was not required to be registered with the HCPC.
- All sonographers working in the service had membership with the Society of Radiographers. The society publishes professional guidance documents and supports the practise of radiography through education and research. In addition, membership provided staff with professional indemnity insurance.
- Staff we spoke with were unsure if they would be supported to undertake further training. However, when we raised this with managers, they told us they would financially support requests for relevant external additional training opportunities.

Multidisciplinary working

- **Staff of different disciplines worked together as a team to benefit women and their families.**
- We observed good multidisciplinary working with referrers, bookings team and reception staff, consultant gynaecologists, sonographers and GPs. All

staff said there was a culture of working together for the benefit of the patient. There was regular contact between all staff and processes to ensure that findings of concern could be escalated and discussed in a timely way.

- Reports were shared between staff working in the gynaecology 'one-stop shop' service through an electronic system and findings were shared with GPs through secure email.
- An incident was investigated with a service lead from the gynaecology 'one-stop shop' service that demonstrated staff worked together to benefit patients.

Seven-day services

- Community Imaging Services Limited (CISL) did not provide emergency ultrasound scanning or tests. This meant services did not need to be delivered seven days a week to be effective.
- CISL offered two sessions for scan appointments each week, with one session being in an early evening. In addition, there were two weekend sessions offered per month. This meant that patients were able to access the service at a range of days and times to suit them. The length of some clinic sessions could be extended to offer additional appointments when the service experienced increased activity.

Health Promotion

- Patients who used the service were supported and empowered to manage their own healthcare and wellbeing through the provision of written and verbal information by sonographers working in the service.

Consent and Mental Capacity Act

- **Women were supported to make informed decisions about their care. Staff understood how and when to assess whether a woman had the capacity to make decisions about their chosen care.** Staff were aware of the importance of gaining consent from women before conducting an ultrasound scan however, the recording of consent in patients' records was not in line with guidance.
- Mental Capacity Act training was available for staff as part of the mandatory training. At the time of our inspection 75% of clinical staff had completed the training. However, following our inspection, the remaining member of staff completed the training and compliance was 100%.
- Staff we spoke with were able explain their responsibility to gain consent from patients before carrying out any procedure and were aware of the procedure for assessing whether patients had capacity to consent to their treatment. Staff understood the requirements of the Mental Capacity Act when making decisions about patient's ability to consent to treatment.
- We observed that consent was gained verbally prior to procedures being completed. However, consent was not consistently documented in patient's records. This was not in line with guidance from The Society and College of Radiographers / The British Medical Ultrasound Society Guidelines for Professional Ultrasound Practice. Revision 3. December 2018. The guidance states that 'verbal valid, informed consent for those examinations of an intimate nature should be recorded in the ultrasound report.' Since the majority of scans were transvaginal, they would be classed as examinations of an intimate nature.

Are diagnostic imaging services caring?

Good

Compassionate care

- **Staff cared for patients with compassion.** Throughout our inspection, we saw patients were treated with compassion, kindness, dignity, and respect. Staff responded sympathetically to queries in a timely and appropriate way.
- We observed caring interactions with patients whilst they were booking in at the main reception or being assisted in the department.
- We saw that patient's privacy and dignity was respected during procedures. Patients undressed in a curtained area in order to maintain privacy and were provided with a paper towel to cover themselves to maintain dignity and protect their clothes from the gel used during the scan procedure.

Good

Diagnostic imaging

- The scan room had a lockable door and curtains around the treatment couch, although we noted that the door was not locked during procedures. There was no engaged sign on the outside of the door, so it was possible that other people could enter the room during the scan. However, the room was within sight of the receptionist and staff said that as the receptionist knew when it was in use, they made sure the room was not accessed by other staff or patients during scan procedures.
- All patients had a health care assistant (HCA) present in the room during the scan procedure, in addition to the sonographer. One of the roles of the HCA was to act as chaperone, which was in line with the service chaperone policy.
- Feedback from patients confirmed that staff treated them well and with kindness. We saw some patient feedback that included comments such as "the best service I have received. I would recommend this clinic to family and friends for the future", "a relaxed atmosphere – reassuring", "better than going to the hospital", and "I got seen quickly, the doctor was informative and friendly".

Emotional support

- **Staff understood the impact that a person's care, treatment or condition may have on their wellbeing and on those close to them, both emotionally and socially.**
- Staff provided emotional support to patients to minimise their distress. Staff supported people through their scans, ensuring they were well informed and knew what to expect. We saw that sonographers took time to explain the procedure to patients and told patients to inform them if they were feeling uncomfortable in order that they could stop the procedure.
- We saw that appointment letters sent to patients provided them with details of their appointment and information about the procedure they were booked for.
- Sonographers spoke with patients throughout the procedure, explaining what they were doing and providing reassurance about the scan findings.

Understanding and involvement of patients and those close to them

- **Staff involved patients and those close to them in decisions about their care and treatment.**
- Patients were communicated with by sonographers to ensure they understood their care and treatment. They were given sufficient time to ask questions and were informed of the findings following the scan. Scan reports were written during the procedure and were immediately available to consultants in the clinic. Patients were made aware that their scan findings would be discussed at their next appointment with the consultant gynaecologist.
- The service allowed for a parent or family member or carer to remain with the patient for their scan if this was necessary.
- Patients were asked to complete a patient satisfaction form by the receptionist following their appointment at the clinic. The satisfaction form referred to their experience of the whole 'one stop' clinic. There was one question on the form which asked patients to rate the sonographer. From January to March 2019, 32 (55%) patients rated their experience as excellent; 23 (40%) rated it as good; 2 (3%) rated it as fair; and 1 (2%) rated their experience as poor. Patients were not asked to provide a written explanation for their rating, meaning the form provided limited details of patient experience. There was no process in place to review the satisfaction form findings so we were not assured that service improvements could be made when a patient rated their experience as poor. A staff member told us they believed the one 'poor' rating would most likely have arisen if a patient had to wait past their scheduled appointment time. However. as there was no supporting evidence, targeted service improvements could not be made.

Are diagnostic imaging services responsive?

Good

Service delivery to meet the needs of local people

- **The service planned and delivered services in a way that met the needs of patients.** The importance of flexibility, choice and continuity of care was reflected in the service provided.
- The facilities and premises were appropriate for the service that was delivered. Clinical areas were easy to access, with clear signage to the correct area of the building. There was free car parking available in a designated car park and on the road outside the GP practice. There was a main GP reception where patients were directed upstairs to the service, and a separate reception area for the gynaecology 'one-stop shop' service which booked in patients attending for ultrasound scans with the service. The waiting area had water, magazines and toilet facilities available for patients and relatives.
- CISL provided some clinics at a weekend or in the evening to accommodate the needs of patients unable to attend during work hours.
- The service was located near established transport routes, with a bus stop a short distance away. Patients were also able to use free and accessible car parking on site or on the road outside the GP practice.
- Signage directing patients to the service from the ground floor GP practice reception was clear, visible and easy to follow.

Meeting people's individual needs

- **The service took account of patient's individual needs.**
- The referral process ensured that the needs of people with a disability or sensory loss had been identified and were highlighted within the electronic referral information. Referrals for patients with protected characteristics under the Equality Act, and those in vulnerable circumstances, were screened by the gynaecology 'one-stop shop' service. Where additional specific support was required, for example, advice from a learning disability nurse, this would be sourced. However, if this additional support could not be accessed, a referral on to the local NHS trust would be made.
- Reasonable adjustments were made so that people with a disability could access and use the service on an equal basis to others. For example, hearing loops were available in the waiting area; a disabled parking bay was provided at the front of the building; the clinic was on the first floor of the building but was accessible to patients with reduced mobility or a physical disability as a patient lift was available; and an interpreting service for patients who did not speak English could be accessed when required.
- Treatment couches were able to take a maximum weight of 140 kg. For any patients in excess of this weight, arrangements were in place for them to be seen at the local acute hospital where there was appropriate equipment to meet their needs.
- There was no specific dementia training required to be completed by staff working in the service.
- We saw that booking administrators sent information with appointment letters about how to get to the clinic with a map and details of the parking facilities. Specific information was provided to patients about what to expect during the ultrasound appointment and about any preparation required, such as arriving with a full bladder.
- There were no specific patient information leaflets about the ultrasound service however, the registered manager told us they hoped to develop some in future. At the time of the inspection there was no website to provide further information for patients.

Access and flow

- **People could access the service when they needed it. Waiting times from referral to treatment were in line with good practice.**
- Referrals were received via a secure NHS email system and were managed by the bookings team who worked for the gynaecology 'one-stop shop' service provider.
- Community Imaging Services Limited worked in partnership with the gynaecology 'one-stop shop' service to minimise the time people had to wait for treatment or care. There was a target to offer appointments to patients within eight weeks of GP referral(or four weeks if deemed urgent). Referrals were triaged by the gynaecology 'one-stop shop' service provider who confirmed if patients needed a scan only, a consultant appointment only, or a scan and see the consultant appointment. The triage process was through consultant review of the referral.

Where possible, patients were contacted by telephone by the gynaecology 'one-stop shop' service to offer a choice of appointment time and location for convenience. Appointment letters were then sent out to patients.

- Managers told us that the gynaecology 'one-stop shop' service monitored and managed the referral to appointment times and that Community Imaging Services Limited did not have any data relating to this. However, service leads confirmed they were always able to offer appointments quickly and were confident that they operated within the target times.
- The service did audit the number of appointments booked, numbers of did not attend (DNA) appointments, and wait times from arrival in the clinic to being seen by the sonographer. For these audits, for the period from April 2018 to March 2019, they provided the following data:
  - Number of scan appointments booked was 1,845.
  - Number of DNA appointments was 137 (this was equal to 7% of all appointments booked).
  - Wait times in clinic were an average of 15 minutes across sites. However, waits were measured from time of arrival at reception to the time when the patient was seen; this was not necessarily a wait after their appointment time, as many patients arrived early for their appointment and did not wait beyond their appointment time.
- The service held a list of patients that were happy to accept appointments at short notice, and these patients were contacted and offered earlier appointments if an appointment was cancelled by another patient.
- There were no occasions of cancelled clinics due to staffing, as there was a bank sonographer who could be contacted to deliver clinics in the event of staff absence.
- The registered manager told us they provided additional Saturday clinics to meet patient need following bank holidays, for example, when the clinic would have been closed.
- Reports were written during the scan appointment, as they were dictated by the sonographer to the health care assistant who worked with them. This meant that scan findings were available immediately to the consultants in the gynaecology 'one-stop shop' service. GPs were sent copies of scan reports by secure email within one week of the appointment.

Learning from complaints and concerns

- **The service treated concerns and complaints seriously**, although they did not report receiving any complaints during the reporting period. However, during our inspection managers explained that the one incident which had been reported was as a result of a concern raised by a patient.
- Managers told us that any complaints would be investigated by them and any learning would be shared with staff. We saw that in the incident where a patient raised a concern, but did not follow it up with a formal complaint, this was discussed with the staff member involved, and learning was also shared with another sonographer in the team.
- The service had a complaints procedure which provided guidance to staff on how to handle patient complaints. There was a service complaints, suggestions and compliments policy and procedure which was dated September 2018, and set out expectations for managing and responding to complaints.
- We saw that there was a complaints leaflet and patient complaint form which detailed how to complain, and the process for managing complaints, including timescales. There was also information about how to escalate complaints to the ombudsman if patients were dissatisfied with the outcome of a complaints investigation.
- The service had a complaints log system which allowed staff to record details of any concerns raised and track the progress of complaints response and resolution.

Are diagnostic imaging services well-led?

Good

Leadership

- **Leaders of the service had the right skills and experience to run the service.** Managerial leadership was provided by the registered manager (RM) and two directors. The leadership team were responsible for the day to day running of the service. Staff knew the management arrangements and their roles and responsibilities.
- Leaders had the capacity, capability and experience to lead effectively. The managers had experience of working within the NHS; the RM as a GP, the deputy manager was a GP practice manager, and the director was a consultant radiologist in a local NHS trust.
- Leaders understood the challenges to good quality care and could identify actions needed to address them.
- Staff told us that the leadership team were visible and approachable. Staff said the service leaders were open and honest with staff and operated an open-door policy.

Vision and strategy

- **Community Imaging Service Limited (CISL) had a vision for what it wanted to achieve.** The vision was to provide a high quality diagnostic ultrasound service with responsive, individualised care within a safe environment. Staff understood the vision and strategy. The longer-term vision was to 'grow' the business to enhance access to the ultrasound service within the gynaecology one-stop shop rapid service model, across the region. The longer-term vision also included an aim to secure direct contracts with other clinical commissioning groups. The service wanted to provide more ultrasound services across different clinical specialties within community environments to improve access for patients.
- The registered manager told us that there was not a current written strategy as they had only been delivering services since October 2018. However, they aimed to develop written strategic objectives to meet the current and longer-term service vision over time.

Culture

- **The managers promoted a positive culture that supported and valued staff, creating a sense of common purpose based on shared values.**
- Staff were positive when describing the culture within the service. They felt supported by all leaders and colleagues within the service.
- During our inspection we saw that staff interacted and engaged with each other in a polite, positive and supportive manner.
- Staff reported feeling supported by the clinical manager, describing them as accessible and supportive. The sonographer we spoke with told us that it was a satisfying job and they felt well supported by a network of staff who worked together to deliver a "…great service."
- The culture centred on the needs and experience of people who used the service and there was open communication following any patient concerns that were raised.
- The sonographers met with the clinical manager every week for peer support. This was an opportunity to discuss any complex cases, any concerns that had been raised, and cover requirements for the forthcoming week.

Governance

- **The service systematically improved service quality and safeguarded high standards of care by creating an environment for clinical care to flourish across most areas of the service.**
- Staff were clear about their roles, what was expected of them, and for what and to whom they were accountable. The clinical lead radiologist had overall responsibility for clinical governance and quality monitoring in conjunction with the Community Imaging Services Limited (CISL) directors.
- There was a governance framework to support the delivery of quality patient care and clear oversight of the day to day working of the service. For example, all staff personnel files contained evidence of appraisals, or those outstanding, which were completed by their substantive employer. Personnel files also contained records of each staff members mandatory training record, care competencies, professional certificates, and disclosure and barring service (DBS) certificates. This meant we were assured that CISL had full oversight of the competencies, skills and capabilities of staff working for their service.

- Working arrangements with the gynaecology 'one-stop shop' service were managed well. There was a written and signed service agreement between CISL and the gynaecology service. This set out the expectations, obligations and terms of the agreement for provision of ultrasound services by CISL. Senior managers for both services held joint meetings and worked in partnership to safeguard high standards of care.
- The management team had held two formal meetings with sonographer staff since October 2018. We reviewed the minutes from the meetings in November 2018 and March 2019. Operational, governance, and performance issues were discussed however, there was no set agenda and the minutes were 'headings' of topics discussed only. There was no record of an action log to monitor progress with any service developments or improvements. The manager stated that due to the team being very small, these were held on a quarterly basis and information was shared on a day to day basis. We observed a schedule was in place to ensure a clinical or management meeting took place monthly in future. This included occasional Saturday meetings for clinicians to attend.
- We reviewed a number of policies that the service had in place including: policy for consent to care and treatment, clinical waste protocol, accident and incident reporting policy and procedure, risk management policy and procedure, good governance policy, and the complaints, suggestions, and compliments policy and procedure. All the policies were within date, and were version controlled.
- We found some policies contained information that conflicted with another policy. For example, the accident and incident reporting policy and procedure dated December 2018, stated that an 'accident and incident log' should be completed in the event of an accident or incident. However, the risk management policy and procedure also contained information about the reporting of accidents and stated that a 'significant event/complaint' form should be completed, which was included in the policy. In addition, the accident and incident reporting policy did not outline what may constitute an incident or the timeframe for investigation. Although governance processes were in place, information contained in some policies was not always consistent or clear, meaning that staff may not easily be able to follow the guidance contained within them.

Managing risks, issues and performance

- **The service had processes to identify, understand, monitor and address current and future risks.** The service had effective arrangements in place for identifying and recording risks. The risks and their mitigating actions were discussed with the wider team.
- The directors of the service held a log of identified internal and external risks. Assessments were completed for any identified risks. At the time of our inspection, two external risk assessments had been completed, which were health and safety, and fire. We saw that both risks had been graded as 'low risk', and any recommended actions had been implemented. For example, the health and safety risk assessment found that work areas must be free from excessive paper materials and, during our inspection, work areas were tidy with only required materials in use.
- The risk templates used for risk assessment listed the risk identified, control measures, and the risk assessment date. The risk assessments were shared with staff when they were initially completed, and again if there were any changes or updates.
- In addition, a business continuity risk assessment and recovery plan dated March 2019, highlighted areas of risk to the effective management of the service. For example, direction was provided for staff to follow in the event of, for example, the incapacity of clinicians; loss of the electricity, telephone, or gas supplies.
- There were appropriate policies in place regarding business continuity, which outlined clear actions staff needed to take in the event of major incidents such as extended power loss, or a fire emergency.
- The service did not report formal key performance indicators directly to commissioners as they did not directly hold a service contract with them. They were required to monitor and report their performance to the lead contract provider as part of their service agreement. This included the number of sessions provided per month, and the number of scans

performed per session, including did not attend rates. Managers told us there had been two meetings to date to review the contractual agreement, which included a review of performance. In addition, managers from the two services met every week to discuss any operational issues and ensure that the service was delivered in partnership.

- The service collated some patient feedback and planned to review both patient and staff feedback during 2019 to help identify any areas for service performance improvements and ensure they provided an effective service.

Information management

- **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 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. Information was on display in the waiting area to advise patients of the service's responsibility for accuracy and safe-keeping of records.
- Community Imaging Services Limited (CISL) 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.
- Electronic patient records were accessed easily but were kept secure to prevent unauthorised access to data. All referrals and reports were stored on an electronic system which was password protected. We observed that staff kept computers locked when not in use. Data was stored electronically, which allowed the service to collate and audit information to improve the quality of care provided
- The directors told us they transferred all scan images from the ultrasound machines onto an external hard-drive every six weeks and archived them. The hard drive was owned and securely stored by the provider of the gynaecology 'one-stop shop' service. A password was required to access files on the hard drive. Once they had been transferred, the scan images were then deleted from the ultrasound machines. This process meant that images could be stored securely in line with GDPR, and that images could not be 'lost' in the event of a machine fault or failure.
- Information governance training was part of the mandatory training programme. At the time of our inspection 100% of staff in the service had completed this. Staff we spoke with had a sound understanding of their responsibilities to ensure confidential data was kept safe.

Engagement

- **The service collaborated with partner organisations effectively but there was limited engagement with patients, staff and the public to plan and manage appropriate services.**
- Progress in delivering services against the contractual agreement was monitored through meetings with the lead provider of the gynaecology 'one-stop shop' service, who held the contract with the local commissioning group. The gynaecology 'one-stop shop' service was responsible for monitoring activity and performance and for reporting this to the local commissioning group. Community Imaging Services Limited (CISL) contributed to this process through their meetings with the gynaecology 'one-stop shop' service provider. Managers told us there had been two meetings to date to review the contractual agreement, which included a review of performance. In addition, managers from the two services met every week to discuss any operational issues and ensure that the service was delivered in partnership.
- Women's views and experiences of the sonographer were only gathered through the provision of a rating score in one question on the gynaecology 'one-stop shop' service patient questionnaire. Since this only provided limited feedback information we were not assured that this was an effective method to assist with improving service provision. The service did not have its own website/social media pages to provide a further method of patient feedback on experience, however, the directors told us this was a future ambition for the service.

Good

Diagnostic imaging

- At the time of inspection, staff feedback from individuals working in the service was not routinely collected. This meant that staff did not have a process for informed future service development.
- While team meetings were not held regularly due to staff availability, staff told us they were kept informed of service planning and development. At the time of our inspection, a meeting schedule had been devised to provide regular clinical staff meetings.

Learning, continuous improvement and innovation

- The service had only been established one year prior to our inspection and had only been performing scans since October 2018. There had been limited opportunity for demonstration of service improvement and innovation. However, we saw that following the reporting and investigation of the one clinical incident, changes to practice had been made to further improve the quality of scan reports.
- We saw that the directors took immediate and effective actions to address some of the concerns we raised during the inspection. For example, when we highlighted that consent was not consistently documented, the clinical director told us he would ensure that going forwards, all sonographer's report templates included a section for documenting that patient consent had been gained.

Outstanding practice and areas for improvement

Areas for improvement

Action the provider SHOULD take to improve

- Ensure that all staff consistently follow hand hygiene requirements in line with the service's infection prevention control policy.
- Ensure that regular hand hygiene audits of individual staff are undertaken and findings are shared, in line with best practise guidance.
- Ensure that all staff consistently document patient consent for procedures, in line with best practice guidance.
- Ensure that information contained in the accident and incident reporting, and risk management policies and procedures, provides clear and consistent information to staff.
- The service should formalise and minute all meetings, including staff meetings within the service, and meetings between the service and the gynaecology 'one-stop shop' provider.
- The service should ensure there are effective processes in place to gather patient and staff feedback, in order to inform service improvements.