# Lucerne Clinic

## Quality Report

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

## Ratings

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

### Mental Health Act responsibilities and Mental Capacity Act and Deprivation of Liberty Safeguards

We include our assessment of the provider's compliance with the Mental Capacity Act and, where relevant, Mental Health Act in our overall inspection of the service.

We do not give a rating for Mental Capacity Act or Mental Health Act, however we do use our findings to determine the overall rating for the service.

Further information about findings in relation to the Mental Capacity Act and Mental Health Act can be found later in this report.

# Summary of findings

## Letter from the Chief Inspector of Hospitals

Lucerne Clinic is operated by International Ultrasound Services Limited. The service provides diagnostic ultrasound for musculoskeletal (MSK) issues, gynaecological and fertility issues, abdominal and thyroid problems, and limited vascular, urinary tract and pregnancy scans (excluding screening scans). The service took referrals from self-paying patients from a wide geographical area, although they were mainly located in London.

The service provides diagnostic imaging for patients aged 18 years and over. It is registered with the Care Quality Commission (CQC) to provide the regulated activity of diagnostic and screening procedures. It has one ultrasound machine in one clinic room.

We inspected this service using our comprehensive inspection methodology. We carried out the announced part of the inspection on 5 October 2019. We gave staff 48 hours' notice that we were coming to inspect to ensure the availability of the registered manager and clinics.

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

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

**Services we rate**

This is the first inspection of this service. We rated it as **Good** overall because:

- The service had enough staff to care for patients and keep them safe. The service-controlled infection risk. Staff assessed risks to patients, acted on them and kept good care records. The service had processes in place to manage safety incidents well and learn lessons from them.
- Staff provided gave patients enough to drink and checked if they were comfortable during scans. Managers made sure staff were competent. Staff worked well together for the benefit of patients. Consent processes were followed and patients were advised on how to prepare for scans. The service was available six days a week.
- Staff treated patients with compassion and kindness, respected their privacy and dignity, took account of their individual needs, and helped them understand their scans. They provided emotional support to patients where necessary.
- The service planned care to meet the needs of their patient population and took account of most patients' individual needs. People could access the service when they needed it and did not have to wait too long for treatment.
- Leaders were approachable and visible. Staff felt respected, supported and valued. They were focused on the needs of patients receiving care. Staff were clear about their roles and accountabilities.

However:

- Although staff understood how to protect patients from abuse and the service worked well with other agencies to do so, the sonographer did not have in-depth knowledge of female genital mutilation (FGM). Therefore, not all staff had training on how to recognise and report all types of abuse, and how to apply it.

# Summary of findings

- Leaders did not operate an effective governance process throughout the service. Staff at all levels were clear about their roles and accountabilities but had no regular opportunities to meet, discuss and learn from the performance of the service. There were no systems in place to monitor mandatory staff training compliance, review and update policies, or monitor the responsibilities of other providers the service worked with.
- Staff did not regularly monitor the effectiveness of care and treatment, or regularly use the findings to make improvements and achieve good outcomes for patients.
- At the time of inspection, the service did not provide information to people on how to give feedback and raise concerns about care they received. The service's policy stated it treated concerns and complaints seriously, but did not state a target timeframe for full response to complaints.
- Leaders and teams did not use systems to manage performance effectively. They identified some risks and issues and identified some actions to reduce their impact, but there was no formalised risk management framework. At the time of inspection, there were no plans to cope with unexpected events.

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

**Dr Nigel Acheson**
**Deputy Chief Inspector of Hospitals (London and South)**

# Summary of findings

## Our judgements about each of the main services

| Service | Rating | Summary of each main service |
|---|---|---|
| **Diagnostic imaging** | Good  | **Diagnostic imaging is the sole core service provided at this location. We rated this service as good because although it required improvements in the well-led domain, it was safe, caring and responsive. We do not rate effective for this type of service.** |

# Summary of findings

## Contents

Good

# Lucerne Clinic

**Services we looked at**
Diagnostic imaging

# Summary of this inspection

## Background to Lucerne Clinic

Lucerne Clinic is operated by International Ultrasound Services Limited.. The service opened in 2016. The service provides diagnostic ultrasound for musculoskeletal (MSK) issues, gynaecological and fertility issues, abdominal and thyroid problems, and limited vascular, urinary tract and pregnancy scans (excluding screening scans). The service took referrals from self-paying patients from a wide geographical area, although they were mainly located in London.

The service has had a registered manager in post since opening in 2016.

We have not previously inspected this service.

The service did not use or store any medications.

## Our inspection team

The team that inspected the service comprised a CQC lead inspector. The inspection team was overseen by Nicola Wise, Head of Hospital Inspection.

## Information about Lucerne Clinic

The service provides diagnostic imaging (ultrasound scans). The service is situated on the ground floor of a centre with other staff including chiropractors, physiotherapists and acupuncturists. The service leases one clinic room for set hours per week. There is a shared reception/waiting area and one shared bathroom. The service is easily accessible by public transport as it is in central London.

The service is registered to provide the following regulated activities:

- Diagnostic and Screening Procedures

All patients accessing the service self-refer to the clinic and are all seen as private (self-funding) patients.

The service was open 10.30am to 12.30pm on Saturdays, and 6pm to 8pm on weekdays.

During the inspection, we visited the registered location in London. We spoke with two staff including the registered manager and a scanning assistant. We spoke with three patients and observed two ultrasound scans. During our inspection, we reviewed five sets of patient records.

There were no special reviews or investigations of the hospital ongoing by the CQC at any time during the 12 months before this inspection. This was the services first inspection since registration with CQC in 2016.

Activity (June 2018 to May 2019)

- In the reporting period, a total of 788 scans took place at the service. Of these, 180 were abdominal/urinary tract scans, 142 were gynaecological, 141 were early pregnancy scans, 91 were musculoskeletal, 60 were testicular/groin, 53 were neck/thyroid, 52 were vascular, and 69 were other pregnancy scans (growth, gender, dating).

Track record on safety for the period June 2018 to May 2019:

- No never events.
- No clinical incidents.
- No serious injuries.
- No incidences of hospital acquired Methicillin-resistant Staphylococcus aureus (MRSA), Methicillin-sensitive staphylococcus aureus (MSSA), Clostridium difficile (c. diff) or Escherichia coli (E-Coli).
- No complaints.

# Summary of this inspection

**Services provided at the service under service level agreement:**

- Provision of the clinic room, including waste removal and cleaning
- Maintenance of ultrasound equipment
- Answering service for telephone enquiries

# Summary of this inspection

## The five questions we ask about services and what we found

We always ask the following five questions of services.

### Are services safe?

Good

This is the first time we inspected this service. We rated it as **Good** because:

- The service controlled infection risk well. Staff used equipment and control measures to protect patients, themselves and others from infection. Clinic staff kept equipment and the premises visibly clean.
- The design, maintenance and use of facilities, premises and equipment kept people safe. Staff were trained to use them. Staff managed clinical waste well.
- Staff completed risk assessments for each patient and removed or minimised risks. Staff identified and quickly acted upon patients at risk of deterioration.
- The service had enough staff with the right qualifications, skills, training and experience to keep patients safe from avoidable harm and to provide the right care and treatment.
- Staff kept detailed records of patients' care and treatment. Records were clear, up to date, stored securely and easily available to all staff providing care.
- The service knew how to manage patient safety incidents, but none had been reported in the 12 months prior to inspection. Staff recognised incidents and near misses and described how to report them appropriately. Managers told us they would investigate incidents and share lessons learned with the whole team. When things went wrong, staff apologised and gave patients honest information and suitable support.

However:

- The service required staff to have mandatory training in key skills but did not have an effective system in place to make sure everyone completed it.
- Although staff understood how to protect patients from abuse and the service worked well with other agencies to do so, the sonographer did not have in-depth knowledge of female genital mutilation (FGM). Therefore, not all staff had training on how to recognise and report all types of abuse, and how to apply it.
- When we asked for records from the premises provider to demonstrate wider environmental cleaning had been completed, there were no recent checklists in place to evidence this.

# Summary of this inspection

## Are services effective?

This is the first time we inspected this service. We do not rate effective for this type of service

- Staff gave patients enough to drink to meet their needs.
- Staff checked to ensure that patients were comfortable during their scans.
- The service made sure staff were competent for their roles. The registered manager appraised the locum sonographer's work performance.
- Staff worked together as a team to benefit patients. They supported each other to provide good care.
- Key services were available six days a week to support timely patient care.
- Staff gave patients advice in relation to their procedure.
- Staff supported patients to make informed decisions about their care and treatment. They followed national guidance to gain patients' consent. They knew how to support patients who lacked capacity to make their own decisions.

However:

- The service provided some care and treatment based on national guidance and best practice but did not regularly update or review these policies.
- Staff did not regularly monitor the effectiveness of care and treatment, or regularly use the findings to make improvements and achieve good outcomes for patients.

## Are services caring?

Good

This is the first time we inspected this service. We rated it as **Good** because:

- Staff treated patients with compassion and kindness, respected their privacy and dignity, and took account of their individual needs.
- Staff provided emotional support to patients, families and carers to minimise their distress. They understood patients' personal, cultural and religious needs.
- Staff supported and involved patients, families and carers to understand their scan results.

## Are services responsive?

Good

This is the first time we inspected this service. We rated it as **Good** because:

- The service planned and provided care in a way that met the needs of the patient population.

# Summary of this inspection

- The service was inclusive and took account of most patients' individual needs and preferences. Staff made some reasonable adjustments to help patients access services.
- People could access the service when they needed it and received the right care promptly.

However:

- At the time of inspection, the service did not provide information to people on how to give feedback and raise concerns about care they received. The service's policy stated it treated concerns and complaints seriously, but did not state a target timeframe for full response to complaints.

## Are services well-led?

**Requires improvement**

This is the first time we inspected this service. We rated it as **Requires improvement** because:

- The service did not have a formal vision for what it wanted to achieve, or a formal strategy to turn it into action.
- Leaders did not operate an effective governance process throughout the service. Staff at all levels were clear about their roles and accountabilities but had no regular opportunities to meet, discuss and learn from the performance of the service.
- Leaders and teams did not use systems to manage performance effectively. They identified some risks and issues and identified some actions to reduce their impact, but there was no formalised risk management framework. At the time of inspection, there were no plans to cope with unexpected events.
- At the time of inspection, there was no system to allow data or notifications to be submitted to external organisations as required.
- The clinic lacked a robust approach to quality improvement.

However:

- Leaders had the integrity, skills and abilities to run the service. They were visible and approachable in the service for patients and staff.
- Staff felt respected, supported and valued. They were focused on the needs of patients receiving care. The service had an open culture where staff could raise concerns without fear.
- The information systems were secure.
- The service engaged with patients and staff but there were limited opportunities for them to plan and manage services.

# Detailed findings from this inspection

## Overview of ratings

Our ratings for this location are:

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

Good

# Diagnostic imaging

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

## Are diagnostic imaging services safe?

Good

This is the first time we inspected this service. We rated safe as **good.**

**Mandatory training**

**The service required staff to have mandatory training in key skills but did not have an effective system in place to make sure everyone completed it.**

All staff apart from one completed their mandatory training at their substantive NHS trust place of employment. We saw evidence that staff had completed and were up to date with most required mandatory training. Staff also completed additional fire awareness, consent and chaperone training locally with the service at the induction stage.

Mandatory training required included: infection prevention and control, fire safety, health safety and welfare, equality diversity and human rights, conflict resolution, safeguarding adults and children, basic life support and the mental capacity act.

The locum sonographer completed his training through his locum agency on an annual basis. We saw evidence of this.

The registered manager did not monitor compliance with mandatory training and so could not alert staff when they needed to update their training. There was no central log or spreadsheet kept of when training would expire.

**Safeguarding**

**Although staff understood how to protect patients from abuse and the service worked well with other agencies to do so, the sonographer did not have in-depth knowledge of female genital mutilation (FGM). Therefore, not all staff had training on how to recognise and report all types of abuse, and how to apply it.**

There were clear safeguarding processes and procedures in place for safeguarding adults and children. A policy was available for staff in a paper format and all staff were required to read this at induction. The service did not see any patients under the age of 18.

At the time of our inspection, 100% of staff were compliant with safeguarding training. All staff had received training in level two of vulnerable adult's safeguarding, and level two for children's safeguarding. The registered manager was trained to level three. This met the intercollegiate guidance 'Safeguarding children and young people: roles and competences for health care staff' (January 2019).

The safeguarding policy did not reference female genital mutilation (FGM). However, these topics were covered in the safeguarding level two course staff completed. The sonographer was not aware of how to identify FGM but did know that a safeguarding referral to be completed when FGM was identified. Following inspection, the provider submitted evidence that they had drafted a comprehensive policy on FGM.

Staff were able to describe the correct pathways as per the providers safeguarding policy to take in the event a safeguarding concern was identified. Staff knew how to make a safeguarding referral and who to inform if they had concerns.

Good

# Diagnostic imaging

**Cleanliness, infection control and hygiene**

**The service controlled infection risk well. Staff used equipment and control measures to protect patients, themselves and others from infection. Clinic staff kept equipment and the premises visibly clean. However, when we asked for records from the premises provider to demonstrate wider environmental cleaning had been completed, there were no recent checklists in place to evidence this.**

The clinic room was clean and had suitable furnishings which were clean and well-maintained. The clinic room had washable flooring and wipe-clean furnishings. The service used fresh paper towelling on the couch for each patient.

If the service needed to use any linens such as gowns, these were washed by the premises provider after staff had left them in an appropriate bin for collection.

We saw a hand sanitiser placed in a prominent position in the scanning room. We observed staff use the hand sanitiser appropriately. Staff followed infection control principles including the use of personal protective equipment (PPE) when performing intimate examinations. All staff involved in clinical work were bare below the elbows.

There was a handwash basin in the ultrasound room and access to hand disinfectant.

However, the service did not complete any hand hygiene audits to ensure that staff were following the World Health Organisation's 'five moments for hand hygiene' recommendations, in line with best practice. There were no handwashing guidance posters available in the clinic room to remind staff of best handwashing techniques.

Staff correctly cleaned and stored equipment such as probes used for intimate ultrasound investigations (for example, transvaginal investigations). Staff covered the probes with an appropriate sheath during investigations and cleaned them with the recommended sporicidal wipes after each ultrasound scan. This eliminated the risk of cross-infection between patients.

We saw records that demonstrated that staff cleaned the equipment and immediate environment before seeing any patients in the clinic room. This included the ultrasound unit, the patient couch, the stool and the work surfaces. The overall deep cleaning of the clinic room was completed by the premises provider's contractor. There was access to cleaning equipment and colour coded mops. Although the environment was visibly clean, we asked for records to demonstrate cleaning had been completed but there were no recent checklists in place to evidence this. The registered manager asked this be reinstated as a result of our inspection. Staff knew how to report and escalate any concerns with cleanliness appropriately.

Although the service did not perform any blood tests or wound care, they did not have the right equipment to clean blood spillages. Following inspection, the registered manager purchased this, in case of emergency within the clinic. A policy was also drafted to instruct staff how to clean up body fluids or blood safely.

There had been no incidences of healthcare acquired infections at the service in the 12 months prior to inspection.

**Environment and equipment**

**The design, maintenance and use of facilities, premises and equipment kept people safe. Staff were trained to use them. Staff managed clinical waste well.**

Patients rang a buzzer to access the reception area. This area had adequate seating for patients and relatives whilst they waited to be called for their scan.

The scanning room included a scanning couch and some chairs. Staff had enough space for scans to be carried out safely. There was one screen to view the images, attached to the ultrasound machine. The ultrasound machine's manufacturer maintained and serviced it annually. We reviewed service records for the equipment, which detailed the maintenance history and service due dates. The service had systems in place to ensure machines or equipment were repaired on time, when needed.

Staff disposed of clinical waste safely. The service did not use sharps, although there was a correctly assembled sharps bin in the clinic room that other providers who leased the space at other times used.

Due to the nature of the service they did not require a resuscitation trolley. However, they did have access to a first aid box at reception.

The service had access to a shared toilet within the building which was clean and well-maintained.

Fire extinguishers were accessible, stored appropriately, and were all up to date with their services. The registered manager was aware of the evacuation procedure in the event of a fire but had not completed any fire assessments or drills since the service had opened.

**Assessing and responding to patient risk**

**Staff completed risk assessments for each patient and removed or minimised risks. Staff identified and quickly acted upon patients at risk of deterioration.**

Staff told us what action they would take if a patient became unwell or distressed while waiting for, or during, an ultrasound scan. All clinical staff were basic life support (BLS) trained. In the case of emergency, the patient would be transferred to the most appropriate neighbouring NHS hospital, using the standard 999 system. At the time of inspection, there was no formal written policy detailing this, but this was put into place following our inspection. The provider also drafted a first aid policy to clarify the expectations of what staff were expected to do in case of accident or injury.

The sonographer described what actions he would take if they found unusual findings on an ultrasound scan. Once the sonographer had identified an abnormal scan, they would create a report which clearly outlined their concerns. In the case of an acute abnormality, the patient would be instructed to attend their nearest emergency department with a copy of the report. In the case of any other abnormal result, a copy of the scan report would be given to the patient for their NHS notes and the sonographer would ring and speak directly to the patient's GP or appropriate healthcare professional. He gave an example of when this had taken place. The report would be sent on directly in cases where the patient had given consent. If a patient did not have a GP, they would be advised to attend the nearest emergency department if appropriate. However, there were no formal written processes or pathways in place to guide staff in this eventuality.

The service ensured that the right person got the right scan at the right time, by asking patients to confirm their identify and date of birth. This evidenced staff followed best practice and used the British medical ultrasound society's (BMUS) 'pause and check' checklist.

The sonographer reported they had not had patients who requested frequent scans. They advised any patients who wanted longer appointments that their scanning time was restricted to 10 -15 minutes as per the BMUS guidance and followed the as low as reasonably achievable (ALARA) principles, outlined in the 'guidelines for professional ultrasound practice 2017' by the Society and College of Radiographers (SCOR) and BMUS.

**Staffing**

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

The registered manager and another locum sonographer completed all the scans. There was always a second member of staff present, in the form of a scanning assistant. The service employed three scanning assistants on zero hours contracts.

The service did not use bank or agency staff. Clinics were planned around the sonographers' availability and to date the service had not cancelled any appointments.

The service's sickness rate from June 2018 to May 2019 was 0%. If needed, the clinic would be cancelled if the sonographer was on annual leave or unwell. The registered manager told us that he would request the help of the locum sonographer if a scanning assistant called in sick, as he lived just around the corner. No lone working took place during operational hours.

The registered manager communicated updates and shift cover requirements using a common application on mobile devices. Staff reported this worked well.

All staff we spoke with felt the staffing levels were sufficient to cover the work required.

There was a formal induction process for new staff, which we saw documented.

**Records**

**Staff kept detailed records of patients' care and treatment. Records were clear, up to date, stored securely and easily available to all staff providing care.**

Patients having all types of scans would receive a report written by the sonographer at the time of the scan in hard

copy, or via email, to add to their NHS notes. Where appropriate, and with consent, the sonographer would also send a copy of the scan report to the patient's GP or another relevant healthcare professionals when making a referral.

The ultrasound machine was password protected. Staff downloaded the images and reports regularly from the ultrasound machine onto an external hard drive and stored this securely in a locked cupboard.

We reviewed five ultrasound reports. Staff recorded information in a clear and correct way. This included the reason for the scan, the findings, conclusions and recommendations.

The service did not keep any paper records. Consent forms were scanned straight away and then shredded. Any electronic records or systems were password protected on a laptop. The laptop and ultrasound machine were kept in a locked cupboard on the premises at all times.

**Medicines**

The service did not store or administer any medicines.

**Incidents**

**The service knew how to manage patient safety incidents, but none had been reported in the 12 months prior to inspection. Staff recognised incidents and near misses and described how to report them appropriately. Managers told us they would investigate incidents and share lessons learned with the whole team. When things went wrong, staff apologised and gave patients honest information and suitable support.**

The service used a paper-based reporting system, with forms available in the clinic for staff to access. The registered manager would be responsible for handling investigations into all incidents.

From June 2018 to May 2019, no incidents were reported at the clinic. Staff we spoke with knew how to report incidents and could give examples of when they would do this. The managers told us they would investigate any incidents and share lessons learned with the whole team via ad hoc team meetings, in person and via the mobile based communication application.

Never events are serious patient safety incidents which should not happen if healthcare providers follow national guidance on how to prevent them. Each never event type has the potential to cause serious patient harm or death but neither need have happened for an incident to be a never event. From June 2018 to May 2019, the service did not report any incidents classified as a never event.

In accordance with the Serious Incident Framework, the service reported no serious incidents (SIs) from June 2018 to May 2019.

Duty of candour is a regulatory duty that relates to openness and transparency and requires providers of health and social care services to notify patients (or other relevant persons) of certain 'notifiable safety incidents' and provide reasonable support to that person. Staff we spoke with were aware of the duty of candour. There had been no incidents when statutory duty of candour had to be used since the service had opened.

## Are diagnostic imaging services effective?

This is the first time we inspected this service. We do not rate effective for this type of service.

**Evidence-based care and treatment**

**The service provided some care and treatment based on national guidance and best practice but did not regularly update or review these policies.**

We reviewed the service's existing policies and protocols relating to: infection prevention control, information governance, concerns and complaints, raising concerns, recruitment, risk assessment, and safeguarding adults. Staff had to sign and date a checklist to confirm they had read policies when they started at the service at induction. However, none of these policies had a date of drafting, review date indicated, or version control. In interview, the registered manager stated that the policies had not been reviewed since the clinic was opened in 2016, as there had been no changes in best practice or evidence base regarding ultrasound scans. There were no written policies or protocols regarding what to do in the event of a deteriorating patient or emergency situation, what to do in the event of an abnormal scan result, or who would be accepted for what types of scans at the

service. The registered manager could articulate these but nothing formal had been drafted to record them. This meant there was a risk in inconsistency in practice between different staff members and that procedures at the clinic would not reflect current national best practice.

The safeguarding policy did not reference female genital mutilation (FGM) and staff we spoke to on the day of inspection were not aware of what to look for in patients regarding this, although they were aware of the wider safeguarding processes surrounding how to report this and how to make a safeguarding referral.

The service followed as low as reasonably achievable (ALARA) principles outlined by the Society and College of Radiographers. The registered manager told us that frequent scans did not occur and that scans were time limited. Following inspection, the service submitted a formalised policy that clearly laid out how the service would follow ALARA principles.

**Nutrition and hydration**

**Staff gave patients enough to drink to meet their needs.**

Staff gave women information on drinking water before a fertility or pregnancy scan to ensure they attended with a full bladder which enabled the sonographer to gain a better view of the womb. In the case of fasting (for four hours) before a liver scan, diabetic patients were instructed that they could have a sugary supplement to maintain their blood sugar levels.

Patients had access to drinking water in the reception area. The service offered water to women who were required to have a fuller bladder at the time of the scan.

**Pain relief**

**Staff checked to ensure that patients were comfortable during their scans.**

Staff did not formally assess pain levels of patients as the procedure was pain-free. However, we observed staff checking frequently with patients that they remained comfortable during the course of their scans.

**Patient outcomes**

**Staff did not regularly monitor the effectiveness of care and treatment, or regularly use the findings to make improvements and achieve good outcomes for patients.**

The service did not have a clinical audit schedule in order to monitor patient outcomes and experience. The provider told us that they performed quarterly audits of ultrasound images and reports, but on the day of inspection, the registered manager told us that the last audit had taken place in 2018. Following inspection, we saw evidence that the registered manager had started to review scans again and audit them for quality. In this most recent audit, only one of the 36 scans was found to have problems with image quality. A total of 10 reports were found to contain minor errors or areas for improvement. The registered manager fed these findings back directly to the locum sonographer for action. There was no external review of images to ensure their quality.

When sonographers identified any unusual or abnormal images, they called the patient's GP and followed up the outcomes to both offer support and to assess the accuracy of the diagnoses through a phone call or email communication. We saw that a meeting had been held in August 2019 to discuss any interesting cases or scan results.

**Competent staff**

**The service made sure staff were competent for their roles. The registered manager appraised the locum sonographer's work performance.**

There were arrangements in place for supporting new staff at the service. We viewed induction records for staff, which included instruction on information governance, the service's safeguarding policy, fire safety, infection control, obtaining consent, chaperoning and concerns and complaints. Staff that we spoke to were satisfied with the induction process and how it prepared them for their role.

All staff received an annual competency assessment and appraisal within their substantial posts in the NHS Trust, apart from the locum sonographer. Following inspection, we asked for evidence of the locum sonographer's

appraisal. We were provided with a copy of an appraisal carried out by the registered manager in October 2019. The service did not carry out any appraisals for other staff specifically relating to duties undertaken at the location.

Staff did not complete any continuing professional development (CPD) or training relating specifically to their work at the service, but confirmed they did so as part of their NHS practice. The locum sonographer had identified that he would like to extend his role and go on a course relating to early pregnancy scanning in his most recent appraisal.

Both sonographers were registered with the Health and Care Professions Council (HCPC) as they were also radiographers by background.

**Multidisciplinary working**

**Staff worked together as a team to benefit patients. They supported each other to provide good care.**

On the day of inspection, we observed good team working between the sonographer and scanning assistant. Staff told us that there were positive working relationships between all individuals as the service as it was a small team.

The service ensured where the patient had consented for their information to be shared. GPs received a copy of the ultrasound report by post or electronically.

**Seven-day services**

**Key services were available six days a week to support timely patient care.**

The service operated up to six days a week, dependent on patient demand. The service was operational from 6pm to 8pm, Monday to Friday. In addition, the service offered appointments between 10.30am and 12.30pm on Saturdays.

**Health promotion**

**Staff gave patients advice in relation to their procedure.**

There was patient information on diagnostic imaging procedures available on the service's website and in the waiting area.

Patients were provided with information on what actions they needed to take prior to their scan. For example, whether to drink anything in order to have a full bladder to improve the image quality for fertility or pregnancy scans.

**Consent and Mental Capacity Act**

**Staff supported patients to make informed decisions about their care and treatment. They followed national guidance to gain patients' consent. They knew how to support patients who lacked capacity to make their own decisions.**

All staff at the service received basic Mental Capacity Act (2005) training through the NHS or their locum agency, although there was no written policy or guidance in relation to this. Staff were able to verbalise the process to take when they believed a patient did not have the capacity to consent. Staff reported they had never had an incident of a patient lacking capacity to consent.

All patients received written information to read and signed a consent form before their scan. We saw clear signed consent forms for three procedures we witnessed on the day of inspection. The sonographer confirmed names and dates of birth prior to the scan and obtained verbal consent to begin.

## Are diagnostic imaging services caring?

Good

This is the first time we inspected this service. We rated caring as **good.**

**Compassionate care**

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

We observed interactions between staff and three patients prior to, during and following procedures. The sonographer introduced themselves prior to the start of a patient's scan, explained their role and what would happen next. Staff were discreet and responsive when caring for patients. Staff took time to interact with patients and those close to them in a respectful and considerate way. All three patients we spoke with were

consistently positive about the care they received, telling us staff were "friendly" and that they would recommend the service to their family and friends. Patients said staff treated them well and with kindness.

The service had trialled giving patients feedback questionnaires in person at the service but this had not had a very high return rate. Instead, the registered manager told us that they directed people to leave feedback on their website, or through an internet search engine review function. The majority of the 82 reviews on this platform were positive, with patients praising the professional and compassionate attitude of staff.

All conversations during and after an appointment took place in the private clinic room. Patients were greeted at the reception and taken through to the clinic room by staff.

The female scanning assistants acted as chaperones during intimate examinations. A chaperone is a person who serves as a witness for both patient and clinical staff as a safeguard for both parties during an examination or procedure. All staff had received guidance on how to perform this role at the induction stage. The clinic always ensured two staff were on a shift together and the registered manager told us any gynaecological or pregnancy scans would be rescheduled if a female scanning assistant was not available.

**Emotional support**

**Staff provided emotional support to patients, families and carers to minimise their distress. They understood patients' personal, cultural and religious needs.**

During our inspection we observed two appointments. Throughout these appointments the sonographer described what they saw and explained findings in a way the patients could understand. Staff provided reassurance and support for nervous and anxious patients. They demonstrated a calm and reassuring attitude to alleviate any anxiety or nervousness patients experienced. Patients were given 30 minute appointments, though scans often took much less time than this, so as not to rush them.

Patients we spoke with during the inspection told us they felt reassured by the information they were given before their appointment and that it helped them prepare for their scan.

The sonographer described how they would explain distressing findings to the patient following a scan, with sensitivity and the appropriate level of detail. They explained that they would flag any abnormal results but not confirm any suspected cause or diagnosis, and would refer the patient to NHS care. The GP or health professional would then make further investigations based on the findings of shared report, with the patient's consent. However, this protocol was not formally recorded anywhere.

**Understanding and involvement of patients and those close to them**

**Staff supported and involved patients, families and carers to understand their scan results.**

Patients were given clear information and preparation instructions via email before their appointment, as well as clear instructions as to how to arrive to the clinic. All three patients we spoke to told us they felt well informed and prepared before coming for their scan.

The service allowed one other person to be present in the scanning room in addition to the patient, sonographer and scanning assistant.

On the day of inspection, we observed that staff communicated with patients and their relatives in a way they understood. Staff took time to explain the procedure before and during the scan. Patients were given enough time to ask questions and staff answered all questions in a calm, friendly and respectful manner.

The sonographer explained the findings of the scan to the patient during the appointment and checked that they were able to receive the full written report by email, usually later that same day. Patients were able to ring the service at any time, with any clinical issues triaged by the receptionist team to the sonographer, who would call them back to discuss any concerns or issues.

All costs were clearly stated on the provider's website and confirmed with the client prior to a scan being booked.

Good

# Diagnostic imaging

## Are diagnostic imaging services responsive?

Good

This is the first time we inspected this service. We rated responsive as **good.**

**Service delivery to meet the needs of local people**

**The service planned and provided care in a way that met the needs of the patient population.**

The clinic's location was close to public transport links. The service provided information on travelling to the clinic on their website and in emails sent out to patients prior to attending a scan.

The waiting area was comfortable with sufficient seating for patients to wait for their scan. There was fresh drinking water and magazines available. The toilet was visibly clean and accessible, maintained by the building's management team.

Patients could book appointments online or over the phone. The service offered out of hours appointment times, in the evenings and on Saturdays.

**Meeting people's individual needs**

**The service was inclusive and took account of most patients' individual needs and preferences. Staff made some reasonable adjustments to help patients access services.**

All staff had completed the equality and diversity course as part of their mandatory training.

The service was accessible to all including individuals who used wheelchairs, as it was on the ground floor. The couch was adjustable in height to allow easier transfer for patients with limited mobility. The couch in the scan room could accommodate patients with a weight of up to 180kg.

The ultrasound scan room provided a calm and relaxing atmosphere. The room had dimmed lighting to enable the patient to view the images. All three patients we spoke with reported their appointments were long enough for them to ask questions and gain reassurance. There was space within the clinic for private conversations to be held and the sonographer was able to describe how they would handle distressing conversations, but this process was not formally recorded anywhere.

The staff at the clinic had knowledge of patients living with dementia and patients with learning disabilities through their NHS practice. However, there was no written policy at the service regarding patients with enhanced needs and no admission criteria that specified whether these patients would be seen at the service.

There was appropriate space within the building for staff to have private conversations with patients. However, there was no written protocol on what to do in the case of an abnormal scan result or giving distressing news.

The service did not have access to formal translation services. Staff told us that they spoke multiple languages between them, including Arabic, Armenian, Spanish, French and Greek, and that this was one of the reasons they were called 'International Ultrasound Services Limited'. Staff would book patients in with the corresponding member of staff if required, although no medical translation took place, and staff stressed all reports were provided in English. Patients could also bring a friend or relative with them if required. Although the clinic recognised there was a risk with this approach to translation services, the registered manager considered this was proportionate for this type of service.

Chaperones were readily available. The service always ensured a female scanning assistant was present for gynaecological scans.

**Access and flow**

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

Between June 2018 and May 2019, a total of 788 scans took place at the service. Of these, 180 were abdominal/urinary tract scans, 142 were gynaecological, 141 were early pregnancy scans, 91 were musculoskeletal, 60 were testicular/groin, 53 were neck/thyroid, 52 were vascular, and 69 were other pregnancy scans (growth, gender, dating).

The service did not have a waiting list for ultrasound appointments. Patients could self-refer to the service on the same day. Where this was not possible, the scan

would be booked the following day, or whenever was most convenient for the patient. All three patients we spoke to were happy with the choice of appointments and ease of the booking process.

Patients could book their scans through the website, or via telephone or email. Between 9am to 8pm Monday to Friday and 9am to 2pm on Saturdays, any calls to the service went through to a team of outsourced receptionists. These receptionists were from a company who specialised in healthcare services and had been trained by the registered manager to take calls and manage bookings. Outside of these hours, patients could leave a voicemail and the call would be returned the next day. This meant staff responded to most calls within 24 hours. If there was any doubt or question that required more clinical input, the reception team emailed the sonographers, after which they would call the patient directly.

The sonographer gave the results of the ultrasound scans to patients immediately after their scans. Reports were usually sent to patients via email later the same day.

On the day of inspection, we saw patients arrive in the reception area and wait no longer than five minutes for their scan. However, the service did not formally audit the patient waiting times in clinic for staff to call them through.

From June 2018 to May 2019 the service had not cancelled any scans.

**Learning from complaints and concerns**

**At the time of inspection, the service did not provide information to people on how to give feedback and raise concerns about care they received. The service's policy stated it treated concerns and complaints seriously, but did not state a target timeframe for full response to complaints.**

Staff told us that they would deal with informal complaints in the first instance, with attempts made to resolve the complaint locally. In the case of a formal complaint, the service had a policy for handling complaints and concerns. The policy stated complaints would be acknowledged within two working days, but no target date was set for provision of a full response. The policy referred patients who were not happy with the service's response to escalate their complaint to the CQC, but we do not have the powers to investigate or resolve individual complaints.

The service received no formal complaints between June 2018 and May 2019.

There was no information for patients within the clinic room or reception area on how to make a complaint. We also could not find this information on the provider's website. Following inspection, the provider told us they had added information on how to make a complaint to the information they sent to patients before coming for a scan.

All patients we spoke with during the inspection saw no reasons to make a complaint and could not suggest any improvements the service could make.

## Are diagnostic imaging services well-led?

Requires improvement

This is the first time we inspected this service. We rated well-led as **requires improvement.**

**Leadership**

**Leaders had the integrity, skills and abilities to run the service. They were visible and approachable in the service for patients and staff.**

The registered manager was the lead sonographer. He was a manager at a large London NHS trust. The other sonographer was employed as a locum but had been with the service since it opened in 2016 and was described as a co-director. All of the other three employees were scanning assistants who also worked within the NHS. Due to the limited nature of the service, there was no role extension planned for the scanning assistants within the service.

Staff told us they felt well supported by the registered manager, who they worked with on a regular basis. They were approachable and open to new ideas and suggestions for improvement to the service.

**Vision and strategy**

Good

# Diagnostic imaging

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

The service did not have a formal vision, beyond being patient centred and providing high quality scans. There was no formal strategy, but the registered manager told us that the company did not have the capacity to expand the service by employing other sonographers at the current time. In the short term, the service planned to redesign the website, as this contained some outdated information.

**Culture**

**Staff felt respected, supported and valued. They were focused on the needs of patients receiving care. The service had an open culture where staff could raise concerns without fear.**

Staff told us they felt supported, respected and valued. We observed good team working amongst staff on the day of inspection. Staff told us there was a 'no blame' culture. There was a policy on raising concerns that staff were aware of.

There was a strong emphasis on patient centred care. Staff promoted openness and honesty and understood how to apply the duty of candour. Staff were aware of what the term 'duty of candour' meant.

Throughout our inspection, the registered manager responded positively to feedback. They assured us improvements would be made at once following our feedback, and demonstrated this following the inspection. This showed a culture of openness and willingness to learn and improve.

**Governance**

**Leaders did not operate an effective governance process throughout the service. Staff at all levels were clear about their roles and accountabilities but had no regular opportunities to meet, discuss and learn from the performance of the service.**

At the time of inspection, we were not assured that there were effective structures, processes and systems of accountability to support the delivery of good quality, sustainable services.

There was no effective system to review and update policies that were not fit for purpose. None of the service's policies had a date of drafting, review date indicated, or version control. In interview, the registered manager stated that the policies had not been reviewed since the clinic was opened in 2016, as there had been no changes in best practice or evidence base regarding ultrasound scans. There were no written policies or protocols regarding what to do in the event of a deteriorating patient or emergency situation, what to do in the event of an abnormal scan result, or who would be accepted for what types of scans at the service. The registered manager could articulate these but nothing formal had been drafted to record them.

There were no systems for managing and monitoring service level agreements with external companies or third parties. For example, the registered manager did not have processes in place to gain assurance about the cleaning or maintenance of the building. Following our inspection, the registered manager asked for assurances to be put into place.

The registered manager did not monitor staff compliance with mandatory training and so could not alert staff when they needed to update their training. However, staff understood their roles and only carried out duties in line with their competencies.

The service did not have regular minuted team meetings but relied on informal sharing of information as they were a small team, who worked restricted hours. There was no forum to share potential learning from incidents or complaints, although there has not been any since the service opened in 2016. There had been one meeting between the two sonographers in April 2019 which discussed high level governance issues, but there were no formal plans for this to be a regular occurrence.

The service had indemnity and medical liability insurance which covered all staff working within the service for the case of a legal claim.

**Managing risks, issues and performance**

**Leaders and teams did not use systems to manage performance effectively. They identified some risks**

**and issues and identified some actions to reduce their impact, but there was no formalised risk management framework. At the time of inspection, there were no plans to cope with unexpected events.**

The registered manager understood some of the risks relating to the premises, service delivery and business. However, at the time of inspection, these risks had not been documented within a risk management framework. The risks were not documented or reviewed in line with the local risk assessment policy. Following inspection, the provider sent us evidence that an annual review of risks had been undertaken. However, most identified risks were not rated and the risk assessment was not recorded in the format specified by the local policy.

There was no audit programme taking place. The provider told us that they performed quarterly audits of ultrasound images and reports, but on the day of inspection, the registered manager told us that the last audit had taken place in 2018. No other audits took place. Following inspection, we saw evidence that the registered manager had started to review scans again and audit them for quality.

There was no back-up generator on the premises. The registered manager told us that the ultrasound machine did not have a back-up battery in the case of a power cut. The sonographer could not finish and report on a scan in the case of a power cut.

The service did not have a business continuity plan at the time of inspection. Following inspection, a document was submitted that stated that in the event of a power cut, any scans would be terminated and rebooked. In addition, if any scans were perceived as urgent (unlikely due to the nature of the caseload), the patient would be advised to attend the nearest NHS centre.

No fire drills had been undertaken by the clinic staff.

**Managing information**

**The information systems were secure. However, at the time of inspection there was no system to allow data or notifications to be submitted to external organisations as required.**

There was an information governance policy that staff followed. Patients consented for their information to be used and shared in line with the General Data Protection Regulation (GDPR) 2018. This was part of their signed agreement within the form detailing the ultrasound process.

All patients were emailed their scans reports through the company email, which was secure. The sonographers could access reported ultrasound scans easily. The ultrasound machine was password protected. Ultimately, all patient images and reports were recorded on an external hard drive that was locked away and password protected.

All staff had access to the work laptop whilst at work. There were folders containing policies and incident forms on the clinic premises.

The service did not have access to the secure portal. It was unclear how the registered manger would send any notifications or data to the CQC. At the time of inspection, the registered manager told us they had not been required to submit any notifications. Following inspection, the registered manager requested access to the secure portal.

**Engagement**

**The service engaged with patients and staff but there were limited opportunities for them to plan and manage services.**

The service had an easily accessible website where patients were able to leave feedback and contact the service. This showed patients were able to engage with the service online and verbally.

There was no formal mechanism for staff feedback as there were no team meetings or staff survey due to the small size of the service. Staff told us that they would be comfortable suggesting improvements to the service, such as suggesting that a cover that presented an infection control risk be removed from the patient couch.

**Learning, continuous improvement and innovation**

**The clinic lacked a robust approach to quality improvement.**

At the time of inspection, the service lacked reasonable challenge from internal or external sources regarding quality improvement, governance, safety and effectiveness. There was no focus on quality

improvement or innovation. Staff told us that working in the NHS helped them keep up to date with current best practice regarding their roles. However, the provider was responsive to the feedback from our inspection and made some improvements following immediate feedback, such as the implementation of some policies and governance processes.

# Outstanding practice and areas for improvement

## Areas for improvement

### Action the provider MUST take to improve

- The provider must ensure they have a system to monitor compliance levels of the mandatory training of staff within the service.
- The provider must implement a system to implement, review and update policies and procedures in line with national guidance.
- The provider must ensure that sonographers have received training in relation to female genital mutilation.
- The provider must strengthen governance and risk management processes to ensure improved assurance around the safety and quality of the service.

### Action the provider SHOULD take to improve

- The service should update all policies to reference and reflect up to date legislation, accurate information and national guidance, including the complaints policy and safeguarding policy.
- The provider should display clear information in the clinic environment about how to raise a complaint.
- The provider should consider holding regular meetings with staff in order to improve governance and strengthen engagement.

This section is primarily information for the provider

# Requirement notices

## Action we have told the provider to take

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

| Regulated activity | Regulation |
| --- | --- |
| Diagnostic and screening procedures | Regulation 12 HSCA (RA) Regulations 2014 Safe care and treatment |

| Regulated activity | Regulation |
| --- | --- |
| Diagnostic and screening procedures | Regulation 17 HSCA (RA) Regulations 2014 Good governance |