The Gynaecology Ultrasound Centre

Quality Report

137 Harley Street
London
W1G 6BF
Tel:0207 7250521
Website: www.ultragyn.co.uk

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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	Requires improvement
Are services safe?	Requires improvement
Are services effective?	
Are services caring?	Good
Are services responsive?	Good
Are services well-led?	Inadequate

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.

Summary of findings

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

Overall summary

The Gynaecology Ultrasound Centre is operated by The Gynaecology Ultrasound Centre Limited. Facilities include two clinical rooms for examinations and ultrasound scanning. There is a changing cubicle and a clinical storage area in each room.

The Gynaecology Ultrasound Centre is a standalone service and provides a private clinical and diagnostic service for women with concerns about their gynaecological health, including early pregnancy. It does not provide a service to NHS patients. The centre offers transvaginal and transabdominal scanning as well as two and three-dimensional scans where appropriate. Most women are referred by their consultant or GP. It provides gynaecological diagnostic services to women and children under 18 years of age.

We inspected this service using our comprehensive inspection methodology. We carried out the unannounced part of the inspection on 22 January 2019.

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

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

The main service provided by this hospital was diagnostic imaging.

Services we rate

We rated this service as **Requires improvement** overall.

We found areas of practice that were inadequate in this service:

- Systems for the management and referral of safeguarding concerns did not reflect current best practice in relation to safeguarding adults.
- The providers statement of purpose did not reflect its services for patients under 18 years of age.
- At the time of inspection, the provider did not have a safeguarding children policy in place, despite treating patients under the age of 18.
- At the time of inspection, the service had no process in place to audit infection control measures, including hand hygiene and regular cleaning.
- The service did not follow best practice when storing medicines.
- At the time of inspection, the provider did not have a formal incident reporting mechanism in place which
- Policies, procedures and guidelines did not always reference current legislation, evidence-based care and treatment or best practice.
- The service did not always make sure staff were competent for their roles.
- Staff had not completed dementia or learning disability awareness training. The service planned and provided services in a way that met the needs of local people.
- Risk and audit were not embedded within the management of the service and there was a lack of overarching governance.
- The service did not have systems to identify risks, plan to eliminate or reduce them, and cope with both the expected and unexpected.

However, we found the following areas of good practice:

- The clinical environment was visibly clean and tidy and staff decontaminated ultrasound equipment after use.
- The service had sufficient staff to provide the right care and treatment.
- Recent audits demonstrated effective and safe practice.

Summary of findings

- Staff were aware of the importance of gaining consent from patients before conducting any procedures.
- Staff worked well together to place the patients at the centre of service and ensure their comfort and satisfaction.
- Staff were supportive, caring and ensured patient's privacy and dignity was maintained.
- The service planned and provided services in a way that met the needs of those who used the service.
- The manager promoted a positive culture that supported staff and created a sense of common purpose based on shared values.
- The service engaged well with patients and staff.

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 that affected this service. Details are at the end of the report.

Prior to the publication of this report the provider provided evidence that it was in the process of addressing the concerns we had raised with them.

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	Requires improvement 	Ultrasound scanning was the only core service provided. We rated this service as requires improvement overall. We rated well-led as inadequate and safe as requires improvement. We rated caring and responsive as good. Effective was not rated. Systems for the management and referral of safeguarding concerns did not reflect current best practice. There was no safeguarding children policy in place and staff did not have the appropriate level of safeguarding training. The service did not have an incident reporting mechanism in place. Policies, procedures and guidelines did not always reference current legislation, evidence-based care and treatment or best practice. The providers statement of purpose did not reflect its services for patients under 18 years of age. The service did not systematically improve service quality and there was a lack of overarching governance. The service did not have systems to identify risks, plan to eliminate or reduce them. However, we also found the service had enough staff to provide the right care and treatment. Staff cared for patients with compassion. Feedback from patients confirmed that staff treated them well and with kindness. Managers promoted a positive culture that supported and valued staff. The service engaged well with patients and staff.

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Background to The Gynaecology Ultrasound Centre

The Gynaecology Ultrasound Centre is a standalone independent private service in central London and accepts self-referrals as well as referrals from consultants and general practitioners. The service opened in 2003 and registered with CQC in 2013.

The service is registered for diagnostic and screening procedures. During our inspection the provider informed us they were also providing scans for children under 18 years of age, this was not recorded on their statement of purpose.

The service has had a registered manager in post since February 2013. This person is also the nominated individual.

Our inspection team

The team that inspected the service comprised a CQC lead inspector, and a specialist advisor with expertise in radiological services. The inspection team was overseen by Terri Salt, Head of Hospital Inspection.

Information about The Gynaecology Ultrasound Centre

The registered location was registered to provide:

- Diagnostic and screening procedures
- Family planning

We inspected the registered location in Harley Street, London. We spoke with eight staff including the nominated individual/registered manager and clinic manager. We also spoke with health care assistants, secretarial staff and medical staff.

We spoke with two patients and reviewed two patient records.

There were no special reviews or investigations of the service ongoing by the CQC at any time during the 12 months before this inspection. The service was not previously inspected since registration with CQC in 2013.

Activity (1 January 2018 to 31 December 2018)

- The service performed ultrasound scans on 10,671 adults and 218 on patients under 18 years of age.
- All activity within the service was privately funded and no NHS patients were treated.
- There was a combined reception and waiting room on the ground floor. The two clinic rooms were on the first floor, which was accessible by stairs or lift.

The clinic manager, deputy clinic manager, secretary and healthcare assistants worked full time at the service. The registered manager was a consultant and worked part time at the service. Eight consultants worked at the service under practising privileges.

The service did not use any medicines and therefore they did not have an accountable officer for controlled drugs (CDs).

Track record on safety between 1 January and 31 December 2018:

- There were no Never Events
- No serious injuries
- No incidences of healthcare acquired Meticillin-resistant Staphylococcus aureus (MRSA).
- No incidences of healthcare acquired Meticillin-sensitive staphylococcus aureus (MSSA).

Summary of this inspection

- No incidences of healthcare acquired Clostridium difficile (C.diff).
- No incidences of healthcare acquired E-Coli.
- Three formal complaints which were upheld.

Services accredited by a national body:

- The service had no accreditation by a national body.

Services provided at the centre under service level agreement:

- Clinical and or non-clinical waste removal.
- Laundry.
- Maintenance of medical equipment.
- Oxygen supply.
- Pathology.
- Information technology support.

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?

Requires improvement 

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

- Systems for the management and referral of safeguarding concerns did not reflect current best practice in relation to safeguarding adults.
- At the time of inspection, the provider did not have a safeguarding children policy in place, despite treating patients under the age of 18. They submitted one following inspection.
- At the time of our inspection, the provider had no access to staff trained at level three safeguarding children. However, following inspection we were informed that the designated safeguarding lead completed level three safeguarding training.
- All other members of staff had level one safeguarding adults and children training despite the fact that they acted as chaperones.
- At the time of inspection, the service had no process in place to audit infection control measures, including hand hygiene and regular cleaning. The provider submitted a clinical audit tool following inspection which identified areas for regular audit.
- Resuscitation equipment was in three different places and was not readily accessible.
- The service did not follow best practice when storing medicines.
- The provider did not have a formal incident reporting mechanism and told us they dealt with incidents as they arose but were unable to provide evidence of any such incidents.

However, we also found:

- All consultants with practising privileges had current level 2 safeguarding adults and level 2 safeguarding children training as part of their employment within the NHS.
- Staff we spoke with knew how to identify and escalate adult and child safeguarding issues if they arose.
- The provider had systems in place which ensured patient identification was confirmed against three points of patient identity including full name, date of birth and address.
- The clinical environment we visited during our inspection was visibly clean and tidy and staff decontaminated ultrasound equipment after use.
- The service had sufficient staff to provide the right care and treatment.

Summary of this inspection

Are services effective?

We do not rate effective.

We found:

- Policies, procedures and guidelines did not always reference current legislation, evidence-based care and treatment or best practice. They were not routinely updated or version controlled.
- Managers did not consistently monitor the effectiveness of care and treatment and use the findings to improve them.
- The service did not always make sure staff were competent for their roles.
- Staff told us they had not completed any dementia or a learning disability awareness training.
- The provider did not have a Mental Capacity Act 2005 (MCA) policy in place and non-clinical staff did not Mental Capacity Act training included in their mandatory training.

However, we also found:

- Recent audits of early scan safety and hysterosalpingo contrast demonstrated effective and safe practice.
- Staff were aware of the importance of gaining consent from patients before conducting any procedures. We observed staff gaining consent from patients prior to starting their ultrasound scan.

Are services caring?

Good

We rated caring as **Good** because:

- Staff were supportive, caring and ensured patient's privacy and dignity was maintained.
- Staff had sufficient time to support patients.
- Staff provided emotional support to patients to minimise their distress.
- Staff involved patients and those close to them in decisions about their care and treatment.

Are services responsive?

Good

We rated it as **Good** because:

- The service planned and provided services in a way that met the needs of people receiving the service.
- People could access the service when they needed it.
- The service treated concerns and complaints seriously and investigated them in accordance with the provider's complaints policy.

Are services well-led?

Inadequate

We rated well-led as **Inadequate** because:

Summary of this inspection

- The provider's statement of purpose did not reflect its services for patients under 18 years of age.
- Risk and audit were not embedded within the leadership of the service.
- The service did not systematically improve service quality and there was a lack of overarching governance.
- The service did not have systems to identify risks, plan to eliminate or reduce them, and cope with both the expected and unexpected.
- The service did not have an incident reporting mechanism and so it was not possible to detect incident themes and patterns and learn from them.

However, we also found:

- The manager promoted a positive culture that supported staff and created a sense of common purpose based on shared values.
- The service engaged well with patients and staff.

Detailed findings from this inspection

Overview of ratings

Our ratings for this location are:

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

Requires improvement

Diagnostic imaging

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

Are diagnostic imaging services safe?

Requires improvement

We previously did not have the authority to rate this service. However, on this inspection we did have authority to rate and we rated safe as **requires improvement.**

Mandatory training

- **The service provided mandatory training in certain areas to staff all of whom had completed it.**
- The provider did not have a policy for mandatory training and mandatory training comprised of first aid; safeguarding adults and safeguarding children level 1; equality and diversity and General Data Protection Regulation(GDPR). Staff told us this training was via e-learning and they could complete this during the course of the working day.
- Data submitted following inspection showed that there were six staff eligible to complete this training. Of these, three had completed first aid and five had completed equality and diversity and GDPR training.
- The providers statement of purpose did not specifically relate to staff training in order to meet the needs of patients under the age of 18 years. We did not see any additional training for directly employed staff to support this activity. Consultants with practising privileges had completed relevant training in their substantive employment.

Safeguarding

- **Staff we spoke with understood how to protect patients from abuse, however systems for the management and referral of safeguarding concerns did not reflect current best practice in relation to safeguarding adults and the provider had no safeguarding children policy in place.**
- The service did not have a formal system in place where alerts for known safeguarding concerns could be activated and the provider had no links to external advice or guidance in relation to safeguarding children.
- At the time of inspection, the provider did not have a dedicated safeguarding children policy or protocol in place. There was brief reference made to safeguarding children in the incident reporting policy but the guidance referred to [Department for Children Schools and Families 2006] was out of date.
- Following inspection, the provider submitted their safeguarding children policy. This identified the safeguarding lead and gave guidance to staff about the different types of abuse. However, the policy also identified a deputy safeguarding lead despite them only having level 1 safeguarding children training.
- The policy did not include any reference to female genital mutilation (FGM). The FGM mandatory reporting duty is a legal duty provided for in the FGM Act 2003 (as amended by the Serious Crime Act 2015). The legislation requires regulated health and social care professionals and teachers in England and Wales to make a report to the police where there are reports or concerns about FGM having taken place.
- The provider had a safeguarding adults protocol which was not dated and had no version control. The

protocol did not relate to key areas in relation to the safeguarding of adults, including female genital mutilation (FGM), forced marriage, domestic violence, modern slavery or on-line protection. Five out of six permanent staff had level I safeguarding adults training and one (designated safeguarding lead) was level 2 trained.

- At the time of inspection, five members of staff, all of whom acted as chaperones, had level 1 safeguarding children training.
- However, according to the 'Safeguarding children and young people: roles and competences for health care staff Intercollegiate document: Third edition: March 2014' which sets out minimum training requirements, all non-clinical and clinical staff who have any contact with children, young people and/or parents/carers should have level 2 safeguarding children training.
- The designated safeguarding lead had level two safeguarding children training and was unaware that the designated lead must have level 3 safeguarding children training for the role.
- Following inspection, we were informed they had completed their level three safeguarding children training.
- Staff could describe some examples of what may constitute a vulnerable person including those at risk of domestic violence and abuse. However, most were unable to describe to us female genital mutilation and signs to be aware of.
- We confirmed that all consultants with practising privileges had current level 2 safeguarding adults and level 2 safeguarding children training as part of their employment within the NHS.
- The provider had systems which ensured patients identification was confirmed against three points of patient identity including full name, date of birth and address. Patient details were also matched against the original referral form. These processes ensured the right person received the right type of scan.

Cleanliness, infection control and hygiene

- **The service did not control infection risk consistently well.**
- At the time of inspection, the service had no process in place to audit infection control measures, including hand hygiene and regular cleaning.
- The provider submitted a clinical audit tool following this inspection. This included audit of areas such as clinical environment; equipment waste and sharps.
- We observed how staff in clinical areas were not always 'bare below the elbows' and there were no infection control audits in place.
- Staff used paper towel to cover the examination couch during a scanning procedure. We observed staff changed this in between each patient. However, they did not clean the examining couch in between patients. We were told couches were cleaned at the end of each day but there was no checklist maintained to confirm this was done.
- We saw staff used disposable gloves during procedures but there was no evidence of aprons being worn.
- The clinical environment we visited during our inspection was visibly clean and tidy. However, there was no cleaning schedule in place.
- We observed staff decontaminating equipment after use. They used an automated machine to sterilise probes. Each probe serial number was recorded on the patient's record in order to provide a tracking system in case of infection.
- The clinical area had dedicated hand washing facilities and staff and patients had access to hand sanitiser.
- There were no reported incidents of healthcare-associated infections reported for this service in the preceding twelve months.

Environment and equipment

- **There were appropriate arrangements for ensuring clinical equipment was maintained and serviced in line with manufacturer guidelines.**
- The provider had resuscitation equipment which included a defibrillator, oxygen and resuscitation drugs. However, these were all kept in separate places; the oxygen was kept in a cupboard on the ground floor; the resuscitation drugs were kept in one clinical

room and the defibrillator was kept in a cupboard in the office along with general files. One member of staff we spoke with was unclear where the defibrillator was kept.

- We pointed this out to the provider who told us this would be remedied by siting a resuscitation trolley in the office for immediate access.
- We were told that all electrical equipment was checked as per safety recommendations. However, the labels to confirm this were not visible on the equipment. A member of staff subsequently showed us these labels which were kept separately in a file. This meant that proof of testing was not readily available for assurance.
- There was a sharps bin in each of the clinical rooms, both of which were undated. These contained sharps and single use equipment. Staff told us the bins were replaced on a regular basis by a private contractor.
- Staff told us they had sufficient amounts of equipment to provide the service and said the equipment they used was of a good standard.

Assessing and responding to patient risk

- **Staff completed and updated medical questionnaires for each patient. They kept clear records and asked for support when necessary.**
- All staff were trained in basic life support and told us they would put their training into use until an ambulance arrived. Since the service started, staff reported no incidences of having to call for an ambulance.
- All patients who underwent a transvaginal ultrasound scan were asked on two separate occasions if they had any allergies to latex. The service had both latex and non-latex covers for the transvaginal ultrasound probe and would select the cover according to the response from the patient.
- The service had clear procedures in place to guide staff on what actions to take if any suspicious findings (whether expected or unexpected) were found on the ultrasound scan performed.
- The provider did not have eligibility criteria for the service; however, a medical questionnaire was used to screen patients and if there were any concerns the provider would refuse treatment and give a full explanation why.
- We observed two scans with patient permission and saw that the patient identification was verified prior to the start of the procedure.

Staffing

- **The service had enough staff to provide the right care and treatment.**
- This was a privately-owned service that offered ultrasound services to self-funding patients. The nominated individual/registered manager worked between one and two days per week. In addition, there were seven consultant obstetricians and gynaecologists who worked on a regular basis at the service under practising privileges.
- There were three healthcare assistants who supported the consultants during each procedure. provider employed a full-time receptionist and two other sessional
- All clinics had at least one healthcare assistant present and a receptionist to greet patients and complete all the necessary records for treatment.
- The service used bank staff infrequently. These were previous employees or staff known to the provider from their NHS clinics. There were 27 healthcare assistant shifts filled by bank staff between 01 September 2018 and 31 December 2018.

  The provider told us there was low usage of agency staff. During inspection, we were told there was no induction handbook or checklist specific to agency staff and they were given a 'tutorial' on the different aspects of the clinic and referred to an 'administration and clinic handbook' which was not updated since 2012.

Records

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

- All patients were given a unique identifying number and a file was created on the provider's database. This contained all clinical records, correspondence and reports, results of investigations and signed consent forms.
- Consultants recorded their findings onto the IT system during the ultrasound scan. They explained to patients that the scan would be sent to the referring doctor that same day. Patients who self-referred were e-mailed their report. If there were concerns raised by the scan then the consultant would spend time with the patient on the day going through the findings. We were told that where there were findings of concern the patient was requested to go to their GP and this was followed up with the patient to ensure they did this.
- Passwords were in place and the user was required to enter a password to gain access to this information. In addition to this step there was a 'firewall' in place to prevent unauthorised external access to the system.
- We reviewed two patient records during the inspection which had been transferred to the providers secure IT system.We found staff recorded all the specified information in a clear and accurate way.
- The provider told us systems were backed up on a daily basis to ensure that data was secure in the event of system failure. A disaster recovery system was in place to ensure that in a disaster situation all critical systems and data remain available.
- All patient records were stored on the clinic database which was remotely backed up. Patient records were required to be stored for a period of 30 years from the point of the last entry into the clinic as a patient.
- All paper patient data that was no longer required was shredded on-site.

Medicines

- **The service did not follow best practice when storing medicines.**
- Local anaesthetic and resuscitation medicines were stored out of their boxes on a shelf in an unlockable cupboard, alongside cleaning materials. There was no temperature control indicator in the cupboard and room temperatures were not checked to ensure they remained at the ambient temperature for safe medicines storage.
- There were no stock control checks done on the medicines and staff confirmed that they would be unable to confirm if any medicine was missing.
- The provider submitted an action plan following this inspection, with actions to be completed by February 2019. This specified that a lockable cupboard to store drugs and medications will be installed. A thermometer will be purchased and temperatures checked regularly to ensure the correct storage of medicines according to the manufacturer's instructions. In addition, there would be a regular stock take and date check of all medicines.

Incidents

- **The service did not always manage patient safety incidents well, staff recognised incidents but did not have any means by which to report them appropriately.**
- At the time of inspection, the provider had an incident reporting policy which outlined the types of reportable incidents, but not the mechanism by which the incidents should be reported.They told us they did not have a formal incident reporting system and said they would deal with incidents as they arose but were unable to provide evidence of any such incidents**.**
- Following this inspection, the provider submitted an incident report form to document and describe incidents.
- There were no never events reported for the service between 01 January 2018 and 31 December 2018. Never events are serious incidents that are entirely preventable as guidance, or safety recommendations providing strong systemic protective barriers, are available at a national level, and should have been implemented by all healthcare providers.
- There were no serious incidents reported for the service between 01 January and 31 December 2018.

Diagnostic imaging

Serious incidents are events in health care where there is potential for learning or the consequences are so significant that they warrant using additional resources to mount a comprehensive response.

- The provider did not apply the Duty of Candour regulation between 01 January and 31 December 2018. The 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.

Are diagnostic imaging services effective?

We do not rate effective for diagnostic imaging services.

Evidence-based care and treatment

- **We reviewed policies, procedures and guidelines produced for the service to implement locally. The manager did not have a system in place to check to make sure staff followed guidance.**
- All staff had access to a policy folder which contained paper copies of the providers policies. We found that some policies and procedures were not routinely updated or version controlled.
- The provider had a clinical audit programme in place, some of which had been completed. For example, we saw results of early scan safety and hysterosalpingo contrast sonography (HyCoSy).
- The early scan audit was carried out in April 2018 on 44 early pregnancy ultrasound examination scans.
- Results of this audit showed there was 100% compliance with safety standards.
- There were 197 HyCoSy procedures carried out between January and December 2017, of which a random sample of 20 cases was audited. The outcome showed 100% completion of the procedure and low complication rates. Antibiotics were given to all patients in accordance with the guideline.
- Eighty per cent of cases had a documented negative pregnancy test. The recommendation was that
- The provider submitted their audit programme which was planned to commence between March and December 2019. This included early scan quality; endometrial thickness measurement; HyCoSy - pregnancy test; early scan safety; diagnosis of miscarriage; quality of reporting.

Nutrition and hydration

- Staff had access to a selection of refreshments (tea, coffee and water) which they provided patients in some circumstances if it was safe to do so.

Pain relief

- Patients were asked by staff if they were comfortable during their ultrasound scans and they were offered additional pillows or assisted to alter positions to aid patient comfort.
- No formal pain level monitoring was undertaken as these procedures are usually pain free. Patients were requested to take in their own pain-relieving medication as a precautionary measure.

Patient outcomes

- **Managers did not consistently monitor the effectiveness of care and treatment and use the findings to improve them.**
- The nominated individual/registered manager told us there was an informal process of audit. They told us they sampled random scans on a regular basis but acknowledged that this was not formally recorded. Where there were any discrepancies, they would verbally address this with the clinician.
- There were no regular audit meetings for consultants to learn from each other or give feedback.

Competent staff

- **The service did not always make sure staff were competent for their roles.**
- The provider appointed staff within the organisation to lead on safeguarding adults and children, infection prevention and control and medicines management. At the time of inspection, none of these members of staff had done any additional training or support to develop their knowledge and skills for these significant roles.

Requires improvement

Diagnostic imaging

- The registered manager told us they appraised staff's work performance to provide them with support and to monitor the effectiveness of the service. However, since staff were appraised annually, we were not assured this was a robust way in which to measure the effectiveness of the service.
- Staff told us they were regularly appraised and information provided by the service showed 100% of staff had received an appraisal within the last 12 months.

Multidisciplinary working

- **Staff with different roles worked together as a team to benefit patients.**
- This was a small service, however we observed that working relationships between clinical and non-clinical staff were positive and professional. Staff worked well together to place the patients at the centre of service and ensure their comfort and satisfaction.

Seven-day services

- The service had taken into consideration the requirement for having a range of appointments available to patients and therefore appointments were scheduled to ensure patients could attend a clinic daytime, evenings and Saturdays.

Consent and Mental Capacity Act

- The provider did not have a Mental Capacity Act 2005 (MCA) policy in place and non-clinical staff did not Mental Capacity Act training included in their mandatory training.
- We saw no reference made to a child being 'Gillick Competent' in any documentation. Children under the age of 16 can consent to their own treatment if they are believed tohave enough intelligence, competence and understanding to fully appreciate what's involved in their treatment. This is known as being Gillick competent.
- We saw that all consultants with practising privileges had completed mandatory training within their NHS role.
- Staff were aware of the importance of gaining consent from patients before conducting any procedures. We observed staff gaining consent from patients prior to starting their ultrasound scan.

Are diagnostic imaging services caring?

Good

We previously did not have the authority to rate this service. However, on this inspection we did have authority to rate and we rated caring as **good.**

Compassionate care

- **Staff cared for patients with compassion. Feedback from patients confirmed that staff treated them well and with kindness**.
- During our inspection, we spoke with two patients following their treatment at the clinic. Feedback about the service was positive with comments including "This was slick; the whole process dovetailed nicely and I only had to take one day off work" and "I would definitely recommend to a friend".
- The environment had been adapted to ensure patients privacy and dignity was maintained.
- The service recently initiated an independent patient feedback survey tool in January 2019 to gather feedback. There were no results available at the time of this inspection.
- We observed how staff did not rush patients who appeared nervous prior to or during the procedure. They provided care that was patient centred and patients clearly appreciated this.
- There was a chaperoning protocol which ensured health care assistant staff were present for all patient examinations. Staff could describe their role and any actions they would take should they have any concerns regarding the conduct of individual clinicians. However, they told us they did not complete any formal chaperoning training.

Emotional support

- **Staff provided emotional support to patients to minimise their distress.**

Requires improvement

Diagnostic imaging

- Staff supported people through their scans, ensuring they were kept well informed and knew what to expect.
- We spoke with staff who told us how providing emotional support to patients was an important aspect of the work they did. There was a quiet room to discuss difficult matters when the need arose.The service told us that patients could stay with a healthcare assistant after receiving bad news. They ensured the patient was in a fit state to travel home and called a taxi for them if required.
- At the end of all procedures, patients were always given advice of what to do if they had concerns around their health and wellbeing. This included advice to contact their consultant or general practitioner if they had concerns following the scan.

Understanding and involvement of patients and those close to them

- Staff communicated with patients to ensure they understood the reasons for attending the centre. All patients were welcomed into the reception area and accompanied to the clinical room by a healthcare assistant.
- Staff told us they encouraged patients to ask questions about their scan. Patients could also access information on different types of scans and packages from the Gynaecology Ultrasound Centre website.
- The provider's website gave information about the consultants who worked at the service; type of service offered and a description of procedures and related costs.

Are diagnostic imaging services responsive?

Good

We previously did not have the authority to rate this service. However, on this inspection we did have authority to rate and we rated responsive as **good.**

Service delivery to meet the needs of people receiving a service

- The service offered a range of appointment times and days, including early evening and Saturday clinics to meet the needs of the patients who used the service. The nominated individual told us there was varied demand for appointment times and in most cases, they could accommodate patient requests.
- Appointments were booked by the secretary who rang each patient and arranged a time which best suited their requirements.

Meeting people's individual needs

- **The service did not always take account of patients' individual needs.**
- There was no translation service readily available if required. Staff told us that where English was not the patient's first language, they were accompanied by a partner or relative who could translate for them. It is not considered best practice to have a relative or carer act as translator for a patient.
- The service rarely treated people living with dementia or with a learning difficulty. Staff could not recall a time when a patient with these needs attended their clinic for an ultrasound scan. They told us that whilst they had not done any awareness training, they would be able to meet the patient's needs.

  We were told the service ensured that appointments for new patients were of sufficient length to allow them time to ask questions.

Access and flow

- **People could access the service when they needed it.**
- We were told that no hard data on waiting times from referral to appointment was maintained since most appointments were arranged within a timeframe to accommodate the patient. They were booked to see the consultant best suited to provide them with clinical assessment and advice.
- In the case of a requirement to conduct an urgent scan the service told us that it would attempt to make an appointment as soon as possible. The service told us

that if there were no appointment slots available and the patient felt they required urgent attention then the service would request doctors to stay after normal opening hours to accommodate the patient.

- Reports were issued on the same day and were sent to the referring doctors by facsimile and regular post. Reports were also sent by e-mail in PDF format, subject to patients' explicit consent. We saw that this consent was clearly documented on the patient's notes.

Learning from complaints and concerns

- The Gynaecology Ultrasound Centre registered manager managed and responded to all formal complaints.
- There was a complaints handling policy which outlined the procedure and how they would be dealt with, depending on the type of complaint. We noted that the provider's complaint policy recommended that where complaints were not resolved to the satisfaction of the complainant, they should contact the Care Quality Commission (CQC). This is inaccurate advice since the CQC does not address individual complaints.
- Complaints were investigated by the nominated individual. The policy stated that complaints would acknowledged within two working days and resolved within 20 working days.
- The provider received a total of three written complaints between 01 January and 31 December 2018 of which there was no recurrent theme. One complaint related to a letter being sent to a patient's former doctor rather than their current one. Staff told us they now ensured that the current referring doctor's name was prominently listed on all patient details.

Are diagnostic imaging services well-led?

Inadequate

We previously did not have the authority to rate this service. However, on this inspection we did have authority to rate and we rated well-led as **inadequate.**

Leadership

- **The manager of the service did not have all of the skills and abilities to run a service providing high-quality sustainable care.**
- There was one service director who was also the nominated individual and registered manager. There was also a clinic manager and deputy manager.
- The nominated individual/manager told us they took full responsibility for overseeing risk and audit. They acknowledged that they did this in an informal way and did not record any actions they may have taken in the past. They told us this was something which they intended to rectify by sharing areas of responsibility with consultants with practising privileges in the service.
- Staff spoke positively about the nominated individual, saying they were approachable and always willing to listen, offer advice and guidance.

Vision and strategy

- The provider had a vision to continue to provide quality care for patients. Staff we spoke with felt they contributed to the provision of a high-quality service.

Culture

- **Staff during our inspection spoke of a positive place to work where staff shared information and worked together well to meet the needs of the patients.**
- The provider had a Duty of Candour policy and there were no duty of candour notifications made between 01 January 2018 and 31 December 2018. They told us apologies would always be offered to the patients and staff would ensure steps were taken to rectify any errors.
- Staff understood their responsibility to be open and transparent with patients when any incidents which met the criteria where formal duty of candour required implementation occurred.

Governance

- **The service did not systematically improve service quality and there was a lack of overarching governance.**

Requires improvement

Diagnostic imaging

- We found areas of concern including the management and referral of safeguarding concerns which did not reflect current best practice in relation to safeguarding adults and children. There was no formal incident reporting system in place and best practice was not followed when storing medicines.
- The nominated individual/registered manager acknowledged that there was what they termed as an 'under-developed' governance framework. For example, the registered manager cited staff appraisals as a measure of the quality of the service.
- At the time of inspection, the provider had no system for maintaining policies and procedures to ensure they were up to date, version controlled and met national guidance. We found a number of polices for example, safeguarding adults protocol, consent forms for different procedures, World Health Organisation checklist for interventional procedures and medical records policy were not dated or version controlled.
- Following inspection, the provider submitted a policy log which included all the service polices with version control and review dates.
- The provider did not have a policy for the safeguarding of children, despite the service seeing patients under 18 years of age.

Managing risks, issues and performance

- **The service did not have systems to identify risks, plan to eliminate or reduce them.**
- The provider had no risk register and when we asked staff for risks within the service, they were unsure what risks there would be. Following inspection, the provider submitted an environmental risk assessment which identified staff and their areas of responsibility.
- The providers incident reporting policy was inadequate for the service and did not reflect the level of risks within the service.
- Between January 2018 and December 2018, the service performed 218 ultrasound scans on patients under 18 years of age. However, this part of the service was not within the providers statement of purpose and no guidance to the public was available for this service.
- The provider did measure some areas of performance, for example, patient waiting time when they came for their appointments as well as patient feedback.
- Patients had access to the providers terms and conditions via the providers website when making a booking.

Managing information

- The provider used secure electronic systems with safeguards to maintain confidential patient information.

Engagement

- **The service engaged well with patients, staff, and the public.**
- The provider's website gave information about the consultants who worked at the service; type of service offered and a description of procedures.
- The service recently engaged with an external company to develop a patient feedback service.

Outstanding practice and areas for improvement

Areas for improvement

Action the provider MUST take to improve

- The provider must ensure that its systems for the management and referral of safeguarding concerns reflect current best practice in relation to safeguarding adults and that all staff understand how to make an adult safeguarding referral.
- The provider must ensure that it implements a safeguarding children policy and all staff receive specific guidance on the policy and how to make a children's safeguarding referral.
- The provider must ensure that any staff member expected to deputise for the safeguarding lead has level three safeguarding children training.
- The provider must ensure it updates its incident reporting policy and procedures and report safety incidents appropriately.
- The provider must ensure its statement of purpose reflects all its service activity and how it meets the needs of patients under 18 years of age.
- The provider must ensure it implements systems to identify risks, plan to eliminate or reduce them, and cope with both the expected and unexpected.
- The provider must ensure it implements a system to systematically improve service quality and governance.

Action the provider SHOULD take to improve

- The provider should improve staff compliance with safe infection prevention and control practices.
- The provider should improve the safe and secure storage of medicines.
- The provider should consider the individual needs of patients living with dementia or with a learning difficulty.
- The provider should not use relatives or carers to act as translator for the patient.
- The provider should improve the availability of resources to support patients who may not use English as a first language.

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 13 HSCA (RA) Regulations 2014 Safeguarding service users from abuse and improper treatment Systems for the management and referral of safeguarding concerns did not reflect current best practice. The registered person must ensure service users are protected from abuse and improper treatment in accordance with this regulation. Systems and processes must be established and operated effectively to prevent abuse of service users. Systems and processes must be established and operated effectively to investigate, immediately upon becoming aware of, any allegation or evidence of such abuse. Regulation 13 (1) (2) (3)

Regulated activity	Regulation
Diagnostic and screening procedures	Regulation 17 HSCA (RA) Regulations 2014 Good governance The service did not systematically improve service quality and there was a lack of an overarching governance framework. The service did not have systems to identify risks, plan to eliminate or reduce them. The registered person must ensure systems or processes are established and operated effectively to assess, monitor and improve the quality of the service and assess, monitor and mitigate the risks relating to the service. Regulation 17 (1) (2) (a) (b)