

# Clinical Diagnostic Services

## Quality Report

104 Harley Street

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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?

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

## Overall summary

Clinical Diagnostic Services at Harley Street is operated by Clinical Diagnostic Services (CDS) LLP. CDS operates ultrasound services across two locations including Harley Street and BMI Hendon Hospital.

The service at Harley Street consists of one scanning and consultation room with an ultrasound machine, an office and shared reception area and waiting room. The service is co-located within other independent healthcare providers.

The service offers advanced ultrasound scanning and transvaginal scanning covering several specialties including general gynaecology and women's healthcare, fertility managements and In Vitro Fertilisation (IVF), early pregnancy assessments and prenatal screening.

The service provides ultrasound services to patients aged 17 and above. A very small proportion of patients were under 17 years old.

We inspected diagnostic imaging services at Clinical Diagnostic Service at Harley Street using our comprehensive inspection methodology. We carried an unannounced visit to the service on 29 October 2018.

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

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

We rated Clinical Diagnostic Services at Harley Street as requires improvement overall.

- The service did not provide mandatory training in key skills to staff.
- There were no comprehensive systems to protect vulnerable people from avoidable harm. Most staff had not completed training on how to recognise and report abuse.

- There was no infection prevention and control policy or auditing of infection control practice. No hand hygiene or cleaning audits had been undertaken.
- We were not assured that staff recognised patient safety incidents. There had been one incident reported for this location in the last 12 months and there had been no evidence of lessons shared in relation to the incident.
- The service did not have comprehensive systems to identify, review and mitigate risks.
- The service had no internal audit program to monitor its processes and identify where action should be taken. There were no policies to address key patient safety issues. In addition, the service did not have a system to review and update policies.
- Although staff informed us the service held regular meetings, minutes from meetings were not always recorded.

However:

- Staff kept detailed records of patients' care and treatment. There were safe systems for sharing diagnostic results. Imaging reports were encrypted and sent by secure email.
- Patients were cared for by experienced staff who maintained appropriate registration with professional bodies.
- The service monitored the quality of its ultrasound services through an appraisal system from referring clinicians. Feedback about the quality of reporting was positive and there were quick report turnaround times.
- Feedback for the service inspected was positive. Staff respected confidentiality, dignity and privacy of patients.
- Services were developed to meet the needs of patients. Staff were aware of people's individual needs and considered these when providing care.

# Summary of findings

- There was a positive culture in the unit and members of staff said they could raise concerns with the leadership team. The service had implemented a number of innovative services and developed these to meet patient's needs.

Dr Nigel Acheson

Deputy Chief Inspector of Hospitals (London and South)

# Summary of findings

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Requires improvement 

# Clinical Diagnostic Services

Services we looked at: Diagnostic Imaging

# Summary of this inspection

## Background to Clinical Diagnostic Services

Clinical Diagnostic Services at Harley Street is operated by Clinical Diagnostic Services (CDS) LLP. CDS provides ultrasound diagnostic scan examination to female and male patients primarily referred from their GP or specialist consultant. The service was registered by the CQC on 27 December 2013.

The unit operated an appointment-based service between 9am and 5pm on Mondays to Thursdays, and

between 9am and 3pm on Fridays. In addition, CDS offered early morning (before 9am), early evening (after 5pm) and weekend appointments on an adhoc basis. The service had a flexible appointment system and patients had a choice out of two clinic locations based on their convenience.

## Our inspection team

The team that inspected the service comprised a CQC lead inspector and a specialist advisor with expertise in imaging. The inspection team was overseen by Helen Rawlings, Head of Hospital Inspection.

## Information about Clinical Diagnostic Services

The service is registered to provide the following regulated activities:

- Diagnostic and screening

During the inspection, we visited the ultrasound unit located at Harley Street. This consists of one ultrasound room, an office, and a shared reception and waiting area.

We spoke with one staff (the director and head of ultrasound services) who was on shift during our inspection. We spoke with three patients and reviewed four sets of electronic patient records.

There were no special reviews or investigations of the service ongoing by the CQC at any time during the 12 months before this inspection. This is the service's first CQC inspection since its registration.

One radiologist and four gynaecologists worked with the provider under practising privileges. There were four sonographers including the service director. All staff work across two locations including Harley Street and BMI Hendon Hospital.

Activity (1 October 2017 to 30 September 2018):

- There were 1700 patient attendances to the unit in the reporting period. Two of these patients were children aged zero to 16 years. The service does not treat NHS patients.

Track record on safety:

- There were no incidents reported in the last 12 months.

# Summary of this inspection

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

We always ask the following five questions of services.

### Are services safe?

We rated safe as requires improvement because:

- The service did not provide mandatory training in key skills to staff.
- There were no systems for safeguarding vulnerable adults and children. Most staff had not completed training on how to recognise and report abuse.
- The service did not conduct hand hygiene audits to ensure staff followed best practice guidelines
- We were not assured staff recognised patient safety incidents. There had been one incident reported for this location in the last 12 months, and there had been no evidence of learnings shared in relation to the incident.

However,

- Staff had access to personal protective equipment and hand gel dispensers were available within the unit.
- The environment was suitable for the services offered. Staff had access to specialist equipment and equipment were adequately maintained.
- Staff kept detailed records of patients' care and treatment
- There were safe systems for sharing diagnostic results. Imaging reports were encrypted and sent by secure email.

Requires improvement



### Are services effective?

We did not rate effective for this service, however, we found that:

- There was no formal consent policy in place. The service did not carry out assessments to decide whether children under 16 years were able to consent without parental permission or knowledge.
- Although there was a range of guidelines and policies for key ultrasound procedures, these were kept at the registered address. Staff had no access to policies on site.
- There was no local audit program in place to monitor compliance with local and national guidelines.

However,

- Patients were cared for by experienced staff who maintained appropriate registration with professional bodies
- There was good multidisciplinary team working in place and with other organisations.

# Summary of this inspection

- The service requested feedback from referrers covering key headlines about the quality of its ultrasound procedures. Feedback about the quality of ultrasound imaging and reporting were positive.

## Are services caring?

We rated caring as good because:

- The unit provided a caring and compassionate service, which involved patients in their care.
- Patients were positive about their experience on the unit. Staff respected confidentiality, dignity and privacy of patients.
- Patients were offered the option of a chaperone when they had internal scans, which made them feel comfortable and reassured.
- Staff provided emotional support to patients to minimise their distress.

Good



## Are services responsive?

We rated responsive as good because:

- Services were planned to meet the needs of patients. The service had a flexible appointment system and patients had a choice of clinic locations based on their convenience.
- The service took account of patients' individual needs. Staff were sensitive to cultural and religious needs of individual patients and made special scan arrangements where necessary.
- People could access the service when they needed it and appointments were prioritised based on their urgency.
- There was a policy in place to deal with complaints promptly and appropriately, although, there had been no formal complaints in the last year.

Good



## Are services well-led?

We rated well-led as requires improvement because:

- The service did not have comprehensive systems in place to identify, review and mitigate risks.
- The service had no internal audit program to monitor its processes and identify where action should be taken. There were no policies in place to address key patient safety issues. In addition, the service did not have a system in place to review and update policies.
- Although staff told us the service held regular meetings, minutes from meetings were not always recorded.

Requires improvement





# Summary of this inspection

- The service promoted research and innovations, however, there were no systems in place to improve services by learning from incidents.

However:

- Staff were positive about the management team. They told us managers were visible and approachable and they could raise concerns with the leadership team.
- Although there was no written vision or strategy for the service, staff were clear about the key organisational value to meet patient needs.
- Managers promoted a positive culture that supported and valued staff.
- The ultrasound service had implemented a number of innovative services and developed these to meet patient's needs.





# 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	Requires improvement	Requires improvement
Overall	Requires improvement	N/A	Good	Good	Requires improvement	Requires improvement

# Diagnostic imaging

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

## Are diagnostic imaging services safe?

Requires improvement 

We rated safe as **requires improvement**.

### Mandatory training

- **The service did not provide mandatory training in key skills to staff.** By the time of our inspection, the service was arranging for staff to complete mandatory training with another provider. There was no definite date set for when this would be completed.
- We noted the service had training records for one ultrasound practitioner who also worked with another healthcare provider. The ultrasound practitioner had completed training in key modules including safeguarding, infection control, preventing radicalisation, moving and handling, mental capacity act, conflict resolution, basic life support and information governance amongst others.
- Senior staff informed us ultrasound practitioners were required to complete training in line with their continuing professional development and these were regularly monitored.
- Following our inspection, the provider informed us they had made arrangements for all staff to attend "the health and safety group" to undergo mandatory training.

### Safeguarding

- **There was no comprehensive system in place to protect vulnerable people from avoidable harm.**

Most staff had not completed training on how to recognise and report abuse. Although the service had a safeguarding lead for children and adults, there was no safeguarding policy in place.

- Information received from the provider indicated 33.5% of staff had completed safeguarding children level 3 training. The same percentage of staff had completed safeguarding adults' level 2 training. This meant most staff had not received the level of training required to be able recognise a child or adult who was at risk or know the process of escalating concerns.
- During our inspection, we reviewed training records for one member of staff, which showed they had completed safeguarding children and adult training. However, this person also worked with another service provider and was not present on the unit at all times. In addition, clinical staff worked across two locations and often worked alone.
- All clinical and non-clinical staff are required to attend adult safeguarding training in line with national guidance. Clinical staff are required to have attended level two adult safeguarding training.
- According to the safeguarding children and young people: roles and competences for health care staff intercollegiate document, all non-clinical and clinical staff who have contact with children, young people or parent and carers require level two safeguarding children training. In addition, staff should be able to access a level three trained professional at any time during their work.
- Senior staff informed us children rarely attended the unit and we noted just two children attended the unit between October 2017 and September 2018.

# Diagnostic imaging

- The service's patient information protocol states that children under 16 years would only be scanned if accompanied by a parent or guardian. In addition, female patients aged 16 to 21 years would only be scanned in the presence of a parent or guardian or female chaperone if the examination involved a male staff and transvaginal ultrasound scanning technique is used.
- We noted the service received information from the local authority's children safeguarding board. We reviewed a correspondence, which discussed empowering professionals to identify girls at risk of female genital mutilation. However, there was no policy in place addressing this issue during our inspection.

## Cleanliness, infection control and hygiene

- **We found variable standards of infection prevention and control (IPC).** All areas of the diagnostic imaging unit were visibly clean.
- Staff informed us they adhered to infection control precautions, such as hand washing and using hand sanitisers, and wearing personal protective equipment (PPE) when caring for patients. However, we noted the sink in the ultrasound room had separate taps for hot and cold water. This was not compliant with infection control guidelines.
- There was an IPC lead in post, however, at the time of our inspection, the service had not completed hand hygiene audits. Hand hygiene audits are carried out when trained members of staff observe staff and patient interactions to ensure all best practice guidelines are followed. Hand hygiene audits provide assurance that good practice is consistently upheld throughout the service.
- There was easy access to personal protective equipment PPE. Gloves were available in the ultrasound room and staff used PPE as required. There was also access to antibacterial hand gels as well as handwashing and drying facilities.
- Staff used paper towel to cover the examination couch during a scanning procedure. Staff changed this in between each patient.
- The provider's patient care protocol outlined how staff should clean ultrasound equipments, in particular,

ultrasound probes. Staff were to clean the transducer and proximal cable with a paper towel and secondly very thoroughly with a specific disinfectant wipe immediately after each scan. The protocol stated that staff should wash their hands with soap and sanitizer before each scan. It also stated staff should wear gloves and apply probe cover when doing internal scans.

- We noted waste management was in line with national standards and we observed a colour coded waste disposal system was in use. There were housekeeping staff for cleaning the unit, however, we did not see a cleaning checklist was in use.
- Only one member of staff had completed mandatory training for IPC.

## Environment and equipment

- **The service had suitable premises and equipment and looked after them well.** The diagnostic unit was located on the ground floor. The unit consisted of a scanning room and an office area. There was a shared reception area and waiting room.
- Diagnostic equipment used in the unit included two ultrasound machines. Senior staff informed us the manufacturer regularly serviced the ultrasound machine and also provided training to staff.
- We checked random pieces of equipment (including dilators, speculum and scissors) and saw they were in their original packages and in date.
- The unit was co-located with another independent healthcare provider and relied on their resuscitation equipment in the event of an emergency. We noted the resuscitation trolley was located on the same floor as the service.

## Assessing and responding to patient risk

- The unit was co-located with another independent healthcare provider and senior staff informed us they had arrangements with this service to assist with medical emergencies. However, there was no formal policy for the management of patients who suddenly became unwell whilst on the unit. Staff informed us patients attended the unit for routine pre-planned ultrasound scan and they had never had to deal with patients who were unwell.

# Diagnostic imaging

- The service had access to the services' resuscitation equipment and they told us they could call for assistance from their staff. Following our inspection, we were provided with a letter from the other healthcare provider stating CDS had access to their resuscitation equipment at all times.
- We noted one member of staff had completed basic life support training to care for patients in an emergency. However, this person also worked with another service provider and was not always present on the unit. In addition, staff worked across two locations and often worked alone at Harley Street.
- Staff were aware of the British Medical Ultrasound Society (BMUS) 'Paused and Checked' checklist which is recommended to be completed prior to an ultrasound scan. We did not see any adapted checklist in use, however, staff informed us they confirmed patient identity prior to a scan to ensure the scan was carried out for the right patient. Staff also confirmed they explained the ultrasound procedure to patients and ensured patients understood the procedure. The provider's patient care protocol highlighted the need for staff to check the patient identity and ensure the patient understood the type of scan to be carried out and the clinical indication for the scan.
- Patients who underwent transvaginal ultrasound scan were asked if they had any allergies to latex. We noted the service used latex free examination gloves and had non-latex covers for transvaginal ultrasound probe.

## Staffing

- **The service had enough staff to provide the right care and treatment.** However, most staff had not completed mandatory training in key skills to manage patient safety issues including safeguarding, infection prevention and control, and resuscitation training.
- CDS director and head of ultrasound services led ultrasound services across two locations. There was one full-time and three part time sonographers, one of whom was the head of ultrasound services. Two full time and three part-time administrative staff provided administrative support on the unit. Two of the administrative staff had completed chaperone training and acted as chaperones where required. There were no vacancies at the time of our inspection.

- During our inspection, we observed that one sonographer was available to cover each location. Staff informed us the service generally ran smoothly and clinics were rarely cancelled. Patients told us they were seen promptly and could book appointments easily. Data provided by the service showed there had been 12 cancellations in the last 12 months due to staff illness.
- The service had five consultants (including one radiologist and four gynaecologists) who worked for the service via practising privileges and attended clinics when they had to see patients.

## Records

- **Staff kept detailed records of patients' care and treatment.** Records were clear, up-to-date and easily available to all staff providing care. Patient records were stored on an electronic record system. We looked at a random sample of four electronic patient records. All records included details of the patient and the clinician referring them. The records also included a registration form signed by the patient, referral from clinicians and a consultation letter providing feedback on the ultrasound findings.
- Once taken, patient images were stored on the ultrasound machines. Staff could access computers and the ultrasound machine on the unit via a password.
- Ultrasound reports were sent to the patient and referring clinician via encrypted email systems and by secured post.

## Medicines

- Staff told us they did not store or administer medicines from this service. Staff informed us consultants involved with ultrasound procedures at CDS sometimes prescribed medication. However, medication was not kept on the premises and patients had to obtain it from their own pharmacy.

## Incidents

- **We were not assured staff recognised incidents and reported them appropriately.** There was no incident policy in place. Staff had reported one incident in the last 12 months. This involved patient reaction to a saline infusion procedure.

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- Following our inspection, we were provided with a “resume of events” and a “duty of candour” report in relation to the incident. The “resume of events” simply outlined a chronology of events. The duty of candour report indicated staff provided support to the patient and contacted the referring clinician. We saw no evidence of learnings shared with the wider team.

## Are diagnostic imaging services effective?

We do not rate effective for diagnostic imaging services.

### Evidence-based care and treatment

- **The service provided care and treatment based on national guidance, however, guidelines were not accessible on site.** Protocols and guidelines were not available or accessible on site. Staff informed us guidelines were kept at the Hendon location and staff could have them faxed to Harley Street if required.
- Following our inspection, we were provided with electronic copies of the services’ protocols and guidelines. The service based its policies and procedures on guidance from professional bodies such as the British Medical Ultrasound Society and the National Institute for Health and Care Excellence (NICE). However, we noted most of the policies we were not dated. In addition, there were no policies in place to address key safety issues such as safeguarding, incidents, infection control and management of patients who suddenly became unwell.
- The service had written local examination protocols for each examination. For example, the gynaecology scan protocol detailed steps to take for different types of gynaecology scans.
- Although the unit did not conduct audits to monitor patient outcomes, the service requested feedback from referrers covering key headlines about the quality of its ultrasound procedures.

### Pain relief

- The service did not provide pain relief to patients. Staff informed us they ensured patients were comfortable throughout the procedure.

### Patient outcomes

- **Managers monitored the effectiveness of care and treatment and used the findings to improve them.** Although the unit did not carry out audits to monitor patient outcomes, the service requested for appraisals/feedback from referring clinicians. We reviewed four recent appraisals from referring clinicians, which addressed key headlines including the quality of staff, quality of diagnostic ultrasound and reporting, and patient feedback. All appraisals confirmed the reports were accurate, detailed and prompt. Referring clinicians indicated the images were clear and enabled them to diagnose and treat patients effectively. Suspicious or clinically relevant findings were promptly relayed to the referring clinician.
- Routine scan reports were usually sent to both the referring clinician and the patient within 24 working hours. Urgent reports were made available immediately. In acute cases, the referring clinician would be contacted directly by telephone.

### Competent staff

- **The service made sure staff were competent for their roles.** Managers appraised staff’s work performance and held supervision meetings with them to provide support and monitor the effectiveness of the service. Data received from the service showed 100% appraisal rate for sonographers in the last 12 months.
- Senior staff informed us they employed only very experienced sonographers with over 25 years’ experience. New staff shadowed an established member of staff for three months. All staff had a disclosure and barring service check and were covered by indemnity insurance.
- Senior staff informed us sonographers were registered with the Health and Care Professional Council (HCPC) and had obtained qualifications as ultrasound specialists.
- Although the service did not have a mandatory training programme for staff, we were told all staff were required to complete clinical training in line with their continuing professional development.

### Multidisciplinary working

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- **Staff of different kinds worked together as a team to benefit patients.** Sonographers, medical staff, administrative staff and referring clinicians supported each other to provide good care.
- Staff informed us they worked closely with patients and referrers to support a seamless treatment pathway. Staff informed us they could contact referring clinicians to discuss relevant issues in relation to patient scans. We reviewed evidence from referring clinicians, which confirmed suspicious or clinically relevant findings were promptly relayed to the referring clinician.
- The service held weekly team meetings to discuss relevant issues regarding the service.

## Seven-day services

- The unit operated an appointment based service, which opened from 9am to 5pm on Mondays to Thursdays, and from 9am to 3pm on Fridays.
- The service also offered early morning, evening and weekend appointments on an adhoc basis.

## Consent and Mental Capacity Act

- The service did not have a formal consent policy. However, patients were provided with a patient registration form, which outlined key details regarding their ultrasound procedure. The form included a section where the patient provided consent for staff to conduct the procedure. Our review of five patient records showed all patients had signed the consent section.
- The service did not carry out assessments to determine whether children under 16 were Gillick competent and therefore, could consent without parental knowledge.
- CDS 'important patient information' document outlined the procedure staff followed when caring for children and young people. Children under the age of 16 years would only be scanned if accompanied by a parent or guardian. Female patients aged 16-21 years would only be scanned in the presence of a parent or guardian or female chaperone if the examination involved a male member of the ultrasound team and transvaginal ultrasound scanning technique was used.

## Are diagnostic imaging services caring?

Good 

We rated it as **good**.

### Compassionate care

- **Staff cared for patients with compassion.** Feedback from patients confirmed that staff treated them well and with kindness.
- We spoke to three patients who attended the unit at the time of our inspection. They said they were pleased with the service and the service was good. They described staff as professional, courteous and kind. They said the scan was dignified and they did not feel awkward. Patients said they were treated with dignity and respect.
- Patients were offered the option of a chaperone, usually of the same gender as the patients. Patients were positive about the presence of a chaperone and said they were professional and engaging.
- Staff informed us patient feedback were mostly positive, however, we noted there was no system in place to review patient feedback and share lessons with staff.

### Emotional support

- **Staff provided emotional support to patients to minimise their distress.** Patients informed us staff were reassuring and made them feel comfortable.
- Patients said clinical staff were professional and experienced and made them comfortable.
- Staff were sensitive to the needs of patients, in particular, patients who were anxious about their fertility treatments or patients who had suffered a miscarriage. Staff informed us they engaged with patients in a comforting and reassuring manner. Staff also referred patients to counselling services.

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

- **Staff involved patients and those close to them in decisions about their care and treatment.** Patients



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reported they were involved in their care and were given clear explanations about ultrasound procedures. They said staff explained procedures and obtained their consent before conducting them.

- We noted patients were provided with clear information about cost and payment options prior to their procedure. All the patients we spoke to said they were aware of the cost.

## Are diagnostic imaging services responsive?

Good



We rated it as **good**.

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

- **The service planned and provided services in a way that met the needs of local people.** The unit operated an appointment based service between 9am and 5pm on Mondays to Thursdays, and between 9am and 3pm on Fridays. In addition, Clinical Diagnostic Services (CDS) offered early morning (before 9am), early evening (after 5pm) and weekend appointments on an adhoc basis. The service had a flexible appointment system and patients had a choice out of two clinic locations based on their convenience.
- Patients informed us they found it easy to book appointments. Patients were provided with “out of hours” emergency telephone number for urgent issues or scanning needs. “Out of hours” phone calls were answered by a clinician who could provide appropriate advice. The service also offered same day service for some urgent referrals.
- There was a referral policy in place. The policy stated that ultrasound scans were usually only carried out with a formal, written referral from a medical doctor or recognised practitioner. The service strongly advised patients to obtain a formal referral from an appropriate practitioner. This ensured clinical back-up was readily available. Patients were able to self-refer, however, request for self-referral scans were assessed by the director of ultrasound services or the practice manager, to ensure it was appropriate to carry out the scan from a clinical and ethical point of view.

### Meeting people’s individual needs

- **The service took account of patients’ individual needs.** Staff were aware of the cultural needs of individual patients and were sensitive to their treatment needs. Staff were sensitive to the religious and cultural needs of individual patients. Special scan examination arrangements were often made for religious people.
- The unit was on the ground floor and there was a ramp for patients to access the building from the main entrance.
- Patients waited in a shared waiting area and we noted the waiting area was spacious with adequate sitting arrangements. Staff offered visitors drinking water were needed.
- Patients were provided with an “Important Patient Information” leaflet, which outlined important information about Clinical Diagnostic Services (CDS) and their scan. This covered information about scan referral, booking appointments, special needs, scan fees, cancellations or delay, emergency scan service, scan results and the grievance policy.
- The service took care of patients’ special needs in a number of ways. Patients were offered a chaperone for all ultrasound examinations, especially those involving internal scan. Patients requiring interpreting services were offered access through external services.

### Access and flow

- **People could access the service when they needed it.**
- The service received referrals from GPs, consultants and other clinicians. Referrals were completed by the referring clinicians and sent to the service.
- The service arranged appointment for referrals deemed to be acute within one to two hours. Appointments for urgent referrals were arranged within 24 hours, while non-urgent appointments were arranged within two to three days.



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- Although waiting times were not audited, patients confirmed they found it easy to book appointments. Patients informed us staff promptly attended to them when they arrived on the unit and they did not have to wait.
- Between August 2017 and July 2018, 12 procedures were cancelled for non-clinical purposes. The most frequent reason for this was identified as illness of the ultrasound specialist.

## Learning from complaints and concerns

- **The service had some systems in place to investigate complaints.** There had been no complaints received between August 2017 and July 2018. Information received from the provider indicated they received “very numerous” compliments, however, the number of compliments were not specified.
- There were feedback forms in the reception area for patients to leave any comments, suggestions or complaints.
- The service had a grievance policy in place for patients to raise any complaints or issues. The policy outlined how patients could raise a complaint and how they were dealt with. However, the policy did not specify timescales for the provider to acknowledge and respond to formal complaints.
- Following our inspection, the provider informed us they had amended their grievance policy to include a timescale of 15 days to respond to any complaint made.

## Are diagnostic imaging services well-led?

Requires improvement 

We rated well-led as **requires improvement**.

### Leadership

- A technical and administrative director led Clinical Diagnostic Services (CDS) across two locations. The director was also the head of ultrasound services. The director was a specialist ultrasound practitioner with skills in the area of gynaecology, reproductive

medicine and pregnancy. The practice manager supported the director and managed administrative staff. The practice manager also acted as the registered manager of the service.

- The service used the same staff across two locations including Harley Street and Hendon. We spoke to two other staff when we visited Hendon. Staff were positive about the leadership of the service, in particular the director of the service. Staff informed us the managers were visible and approachable. They felt well supported by the director of the service. Staff felt confident to approach the management team regarding issues to do with their professional or personal life.

### Vision and strategy

- There was no written vision or strategy for the service at the time of our inspection. However, staff and the management team were clear about the key organisational value to meet the needs of patients. Senior staff informed us they wanted to ensure the service’s continuity and sustainability.
- Their statement of purpose stated that Clinical Diagnostic Services was established with the aim of providing high quality, advanced ultrasound scanning with ready access to appropriate clinical care for patients.

### Culture

- **Managers across the service promoted a positive culture that supported and valued staff, creating a sense of common purpose based on shared values.** Staff felt valued and informed us they worked well as a team. Staff confirmed they worked in a very close-knit team and we noted they had worked for the service for significant number of years.
- Staff reported there was a positive culture within the service. Staff said they worked in a friendly environment.
- Staff recognised the need to be open and transparent with patients when something goes wrong in line with duty of candour requirements.

### Governance

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- The service had a clear organisational structure with a technical director, practice manager and a medical advisory panel. Staff informed us the medical advisory panel conducted meetings annually as well as on adhoc basis to review clinical issues regarding the service.
- The practice manager managed administrative staff and reported to the technical director who also acted as the lead for governance and quality monitoring.
- The service held weekly team meetings to discussed patient management and administrative issues. However, the service did not record notes of meetings and we were unable to review minutes of the service's meetings except for a strategy meeting held in April 2018.
- We reviewed minutes of a CDS strategy meeting held in April 2018. The meeting was held to review clinical practice, patient support and business aspect of CDS practice. We noted some of the issues discussed during the meeting had been implemented during our inspection. This included employment of a full time office manager and implementation of annual appraisal feedback from referring clinicians. The service had also implemented a weekly staff meeting and annual advisory panels (medical and patient care).
- During the strategy meeting held in April 2018, staff also discussed proposed arrangements for CDS staff to access mandatory training provided by another service. This was still in progress at the time of our inspection and there had been no date set for when staff would be able to access the training.

## Managing risks, issues and performance

- **The service did not have comprehensive systems in place to identify risks, plan to eliminate or reduce them, and cope with both the expected and unexpected.**
- At the time of our inspection, the service did not hold a risk register. The service had been in the early stages of completing risk assessments for any risks identified. One risk assessment had been completed for slips and

trips, which covered people at risk, actions taken and further actions required. The building management fire policy for Harley Street outlined actions to be taken in the event of a fire.

- We found several risks during our inspection and there were no mitigating plans in place to address those risks. For example, the service did not provide mandatory training and staff relied on one staff (who had completed mandatory training with another employer) as the reference point for safety issues. There were no policies to address key patient safety issues and no system in place to review and update policies. The service did not have a formal consent policy, although patients signed a registration form consenting to treatment. The service was not assessing children under 16 to determine whether they were Gillick competent and therefore, could consent without parental knowledge.
- Although the provider obtained feedback from referrers in the form of an appraisal of its services, there were no internal systems to learn from incidents. For example, the service had made a duty of candour notification involving patient reaction to a saline infusion procedure. However, we saw no evidence to demonstrate any learning was shared with staff. In addition, the service did not carry out any local audits to monitor its processes.
- There was a business continuity plan, which highlighted contingency plans in the event CDS was unable to operate from Harley Street. All patients were to be contacted and offered alternative appointments at the BMI Hendon Hospital location.
- Following our inspection, the provider informed us they had drawn up a risk assessment policy.

## Managing information

- **The service collected, analysed, managed and used information well to support all its activities, using secure electronic systems with security safeguards.**
- The service was aware of the requirements of managing patient's personal information in accordance with relevant legislation and regulations. The service had systems in place to ensure they were compliant with provisions of the General Data

# Diagnostic imaging

Protection Regulations (GDPR). At the time of our inspection, the service held a current registration with the Information Commissioner's Office for data protection.

- Patient records were stored on secured electronic systems with password access and ultrasound reports were transferred using secure systems.
- Patients were provided with a registration form and an 'Important Patient Information' document, which outlined the services terms and conditions and provided clarity about costs and payment methods.

## Engagement

- **The service engaged with patients, staff, and partner organisations to plan and manage appropriate services.**
- The service held weekly staff meetings where staff discussed patient management and administrative issues. However, staff did not record minutes of meetings as at the time of our inspection.
- Senior staff informed us they regularly engaged with external parties and referrers on an adhoc basis.
- The service engaged with referrers and obtained annual appraisals on key performance indicators. Patients were engaged through feedback forms, although this was not audited. Senior staff informed

us they received many positive feedback from patients and we confirmed this during our interactions with patients. However, it was not clear how the service used patient feedback to improve or share learnings with staff.

## Learning, continuous improvement and innovation

- **Although the service promoted research and innovations, there were no comprehensive systems in place to learn from incidents.**
- The service and its director were recognised for their involvement and pioneering work in developing key technical advances in ultrasound imaging including transvaginal scanning, 3D and 4D volumetric ultrasound amongst others.
- The director was involved in clinical research and had published papers for journals including technical papers for ultrasound machine manufacturers. The service was also recognised for its educational and training programmes and the service director had spoken at several ultrasound clinical meetings worldwide.
- Notwithstanding the service's research and pioneering work, we were not assured of systems to identify, investigate and learn from incidents to improve patient care.

# Outstanding practice and areas for improvement

## Outstanding practice

- The service was recognised for pioneering work in developing key technical advances in ultrasound imaging including transvaginal scanning, 3D and 4D volumetric ultrasound amongst others. The service

was involved in clinical research and its senior staff had published papers for journals including technical papers for ultrasound machine manufacturers.

## Areas for improvement

### Action the provider MUST take to improve

- The provider must take prompt action to address a number of significant concerns identified during the inspection in relation to mandatory training, safeguarding and incident reporting.
- The provider must take prompt action to establish systems and processes to prevent abuse of service users. This includes ensuring staff have completed mandatory training in key skills to be able to recognise and report abuse.
- The provider must take prompt action to ensure the quality and safety of services provided are assessed, monitored and improved. This includes ensuring

incidents are reported in line with the national guidelines and developing systems to investigate and learn from them. In addition, the provider must implement policies to address key safety issues and ensure staff have access to policies on site.

- The provider must take prompt action to ensure that all risks related to patient safety are recorded with actions to mitigate them.
- The provider must take prompt action to ensure audit and monitoring systems are in place to monitor performance and compliance with local and national guidelines.

This section is primarily information for the provider

## Requirement notices

### Action we have told the provider to take

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

Regulated activity	Regulation
Diagnostic and screening procedures	<p>Regulation 11 HSCA (RA) Regulations 2014 Need for consent</p> <p><b>Regulation 11(1)</b></p> <p>The service must provide care and treatment with the consent of the relevant person.</p> <p>The service must carry out assessments to determine whether children under 16 could consent without the need for parental permission or knowledge.</p>
Regulated activity	Regulation
Diagnostic and screening procedures	<p>Regulation 12 HSCA (RA) Regulations 2014 Safe care and treatment</p> <p><b>Regulation 12 (1)(2)(a)(b)(c)(h)</b></p> <p>Care and treatment must be provided in a safe way for service users.</p> <p>The service must provide mandatory training in key skills to staff. The registered person must ensure adherence to infection prevention and control precautions is consistent. The service must implement systems to manage patient safety incidents.</p>
Regulated activity	Regulation
Diagnostic and screening procedures	<p>Regulation 13 HSCA (RA) Regulations 2014 Safeguarding service users from abuse and improper treatment</p> <p><b>Regulation 13(1) (2) (3)</b></p>

This section is primarily information for the provider

## Requirement notices

The provider must establish systems and processes to protect service users from avoidable harm.

### Regulated activity

Diagnostic and screening procedures

### Regulation

Regulation 17 HSCA (RA) Regulations 2014 Good governance

#### Regulation 17(1) (2) (a) (b)

The provider must ensure the quality and safety of services provided are assessed, monitored and improved.

The provider must ensure all risks related to patient safety are recorded with actions to mitigate them.