Direct Medicare UK Limited

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Inspection report

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This report describes our judgement of the quality of care at this service. It is based on a combination of what we found when we inspected, information from our ongoing monitoring of data about services and information given to us from the provider, patients, the public and other organisations.

Ratings

Overall rating for this location	Requires Improvement
Are services safe?	Requires Improvement
Are services effective?	Inspected but not rated
Are services caring?	Good
Are services responsive to people's needs?	Requires Improvement
Are services well-led?	Requires Improvement

Summary of findings

Overall summary

We rated this location as requires improvement because:

- There was a lack of clarity about who was the designated lead in the service for escalating any safeguarding concerns. Not all staff had completed training on how to recognise abuse Staff did not always assess risks to patients, or act on them. Not all information in records was easily available.
- Patient information was not always clear, Staff did not always follow national guidance and service policies for obtaining and documenting patients' consent.
- Staff did not always take account of patients' individual needs and make reasonable adjustments where these were needed. Staff did not always ensure patients had drunk enough water when needed prior to their investigation. Information for patients about how to raise any concerns was not always clear.
- Leaders did not always understand and manage the priorities in the service. Governance systems were unclear and there was a lack of corporate oversight in management of risks and issues across the service. Recruitment procedures did not always follow legislative requirements.

However:

- The service had enough staff to care for patients and keep them safe. Staff had training in key skills, understood how to protect patients from abuse, and managed safety. The service controlled infection risk well and staff kept good care records. The service managed safety incidents and had a process to learn lessons from them.
- Staff provided good care and treatment. Managers monitored the effectiveness of the service and made sure staff were competent. Staff worked well together for the benefit of patients and had access to good information. Key services were available to suit patients' needs.
- Staff treated patients with compassion and kindness, respected their privacy and dignity, took account of their individual needs, and helped them understand their conditions. They provided emotional support to patients, families and carers.
- The service planned care to meet the needs of local people and made it easy for people to give feedback. People could access the service when they needed it and did not have to wait too long for treatment.
- Leaders ran services well using reliable information systems and supported staff to develop their skills. Staff felt respected, supported and valued. They were focused on the needs of patients receiving care. Staff were mostly clear about their roles and accountabilities. The service engaged with patients to plan and manage services and staff were committed to improving services.

Summary of findings

Our judgements about each of the main services

Service	Rating	Summary of each main service
Diagnostic and screening services	Requires Improvement 	We rated this service as requires improvement. See the summary above for details.

Summary of findings

Contents

Summary of this inspection

Background to Direct Medicare UK Ltd

Direct Medicare UK Ltd is a registered location for Direct Medicare UK Limited. The location has been registered since July 2019 to provide the regulated activities diagnostic and screening services and treatment of disease, disorder or injury. The service provides diagnostic ultrasound procedures on a sessional basis at a range of GP and healthcare locations. The registered location does not host any clinics on site but is the provider's main administrative base for delivery of services, which are mainly at sites in the North West and South East of England.

At the time of our inspection, there had not been a registered manager at the location since February 2021.

This was the first inspection since the provider's registration.

How we carried out this inspection

We carried out a comprehensive inspection to assess the provider's compliance with fundamental standards of safety and quality. We looked at key questions of the safe, effective, caring, responsive and well-led domains. We reviewed specific documentation, interviewed key members of staff including the managing director; sonographers, healthcare and administrative staff, and the senior management team who were responsible for leadership and oversight of the service. We also spoke with 12 patients about their experience of treatment and care as a service user.

You can find information about how we carry out our inspections on our website: https://www.cqc.org.uk/what-we-do/how-we-do-our-job/what-we-do-inspection.

Areas for improvement

Action the service MUST take is necessary to comply with its legal obligations. Action a service SHOULD take is because it was not doing something required by a regulation but it would be disproportionate to find a breach of the regulation overall, to prevent it failing to comply with legal requirements in future, or to improve services.

Action the service MUST take to improve:

- The service must ensure that procedures for obtaining consent from the relevant person reflect current legislation and guidance and that staff follow service policy for recording patient consent. Regulation 11(1).
- The service must ensure that clear and accessible information is provided for patients regarding how to raise any concerns or complaint Regulation 16 (1).
- The service must ensure there are effective systems and processes to assess, monitor and improve the quality and safety of the services provided in the carrying on of the regulated activity. Regulation 17 (1)(a).
- The service must review their policies for relevance to the service context and ensure review dates are appropriately identified. Regulation 17(1)(a).
- The service must ensure there are systems and processes that enable them to identify and assess the risks to the health, safety and/ or welfare of people who use the service. Regulation 17(1)(2)(b).
- The service must ensure that recruitment procedures are followed according to service policy and to meet the requirements of Schedule 3 Health and Social Care Act 2008 (Regulated Activities) Regulations 2014 Regulation 19 (2)

Summary of this inspection

Action the service SHOULD take to improve:

- The service should ensure that local safeguarding protocols and escalation processes are reviewed, and an appropriate designated safeguarding lead is identified and available within the service.
- The service should review processes for ultrasound equipment calibration to ensure these are clear.
- The service should ensure information and instructions for patients are clear, including details of any relevant preparation required and communications for appointment bookings.
- The service should review and take action to improve systems for identifying and meeting the individual needs of patients, including any disabilities, sensory disabilities or language needs patents may have.
- The service should continue to develop their vision, values and business strategy and engage staff in this process.

Our findings

Overview of ratings

Our ratings for this location are:

	Safe	Effective	Caring	Responsive	Well-led	Overall
Diagnostic and screening services	Requires Improvement	Inspected but not rated	Good	Requires Improvement	Requires Improvement	Requires Improvement
Overall	Requires Improvement	Inspected but not rated	Good	Requires Improvement	Requires Improvement	Requires Improvement

Requires Improvement

Diagnostic and screening services

Safe	Requires Improvement
Effective	Inspected but not rated
Caring	Good
Responsive	Requires Improvement
Well-led	Requires Improvement

Are Diagnostic and screening services safe?

Requires Improvement

We rated safe as requires improvement.

Mandatory training

The service provided mandatory training in key skills to all staff and made sure everyone completed it.

Staff received and kept up to date with their mandatory training. The service had identified a training matrix for mandatory training in core subjects. Subjects included basic life support, manual handling, infection control, fire safety, and health and safety. Other subjects included safeguarding, equality and diversity, information and security, and incident investigation. At the time of inspection, staff we spoke with were up to date with their mandatory training.

Radiographer and sonography staff received and kept up to date with their mandatory training. The service also held records of mandatory training for any staff who had completed this as part of their main employment in the NHS.

The mandatory training was comprehensive and met the needs of patients and staff. Most of the mandatory training was provided through an electronic learning platform which all staff could access. Some face-to-face learning was provided in certain subjects, the service was looking to further develop face-to-face learning in different subject areas for the future.

Clinical staff completed training on recognising and responding to patients with mental health needs and learning disabilities. Staff we spoke with had a general understanding of the Mental Capacity Act and how this related to any patients who attended the service.

Managers monitored mandatory training and alerted staff when they needed to update their training. The operations manager monitored staff compliance with mandatory training through an electronic system. Staff also received prompts through the electronic system when their mandatory training was due.

Staff we spoke with during inspection said they had to complete their mandatory training in their own time.

Requires Improvement

Diagnostic and screening services

Safeguarding

Staff understood how to protect patients from abuse. Not all staff had completed training on how to recognise abuse and systems for delivering and ensuring this was in place were not always clear.

Staff received training specific for their role on how to recognise and report abuse. All staff in the service were required to complete Safeguarding Children and adults' level 1 and 2. Data requested from the service showed 10 of 16 staff had completed safeguarding level 1 training updates in the days following inspection and all 16 staff had completed safeguarding level 2 training updates in the days following inspection. These training updates were prompted by our inspection.

Staff knew how to identify adults and children who may be at risk of harm.

Staff knew how to make a safeguarding referral and who to inform if they had concerns. The operations manager would note any safeguarding concerns on a day to day basis, although the designated safeguarding lead was external to the service. The service had a safeguarding adult and a safeguarding children policy which referenced appropriate national guidance for safeguarding. The service had identified a safeguarding flowchart which directed staff to raise any safeguarding concerns to the safeguarding lead and to fill out an incident form to the electronic reporting system.

However, there was some lack of clarity regarding who was the designated safeguarding lead for the service. Staff gave different responses regarding the safeguarding lead including that there was no designated lead ; also that one of the directors, who was in full-time employment as a consultant in ENT and a trainee GP outside of the service, was stated as the safeguarding lead, having the required level 3safeguarding training. We also heard the clinical lead for the service would be the safeguarding lead but needed to complete level 3 safeguarding training. The clinical lead had recently returned to the service only 2 months prior to the time of inspection and was currently only working in the service for 3 half days a week. We had some concerns around the practical implementation of any safeguarding issues which may need to be referred to the local authority, given the availability of the staff who were identified as safeguarding leads in the service. Following the inspection, the service provided data which showed all 16 members of staff had completed safeguarding adults level 3 training following inspection, however this would not have been a requirement for every member of staff.

The service had not identified any safeguarding concerns or made any safeguarding referrals since registration.

The service did not treat children however staff were aware of potential safeguarding issues which may present for any children visiting the service.

The service had a document check list to complete for employment of permanent members of staff. This indicated whether the required documentation had been received for the individual, including CV, right to work in the UK, certificate of disclosure and barring service (DBS) checks, 2 references, and evidence of original qualifications and mandatory training completed, and confirmed photographic identification. However, when we reviewed staff files during the onsite inspection, we saw there were inconsistent and unclear records maintained of completed recruitment checks, including a lack of key recruitment documents and evidence for completed enhanced DBS checks for some clinical staff. In records for 4 sonographer staff, there were no employment references evident in one file, another had only one employment reference in their file, the 2 other files had evidence of 2 completed references for staff. For 2 sonographer staff, records contained evidence of a residence permit which indicated 'leave to remain for restricted

work'; 2 of the sonographer staff files did not indicate confirmation of the individual's right to work in the UK. Two sonographer staff files had document checks to confirm the ID for a completed enhanced DBS check, but the original certificate was not included; in the other two sonographer staff files, evidence of DBS check was not seen. We saw that proof of original qualifications, and photo ID were not evident in 1 of the 4 sonographer staff files we reviewed.

Cleanliness, infection control and hygiene

The service controlled infection risk well. Staff used equipment and control measures to protect patients, themselves and others from infection. They kept equipment and the premises visibly clean.

The service provided ultrasound services at clinic sites hosted by GP services. Clinical areas were clean and had suitable furnishings which were clean and well-maintained.

The service completed spot checks at clinic locations and recorded these outcomes as 100% compliant for cleanliness.

Cleaning records were up-to-date and demonstrated that all areas were cleaned regularly.

Staff followed infection control principles including the use of personal protective equipment (PPE).

Staff followed service protocols for managing infection prevention and control risks. We observed staff in clinics were thorough in cleaning equipment before and after each patient use. Staff were attentive to handwashing and use of gloves, masks and aprons in clinical settings.

Staff cleaned equipment after patient contact and had an electronic system to show when equipment was last cleaned.

Environment and equipment

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

Clinics were held at GP and healthcare premises where the design of the environment followed national guidance.

Staff carried out daily safety checks of specialist equipment. The service had a decontamination and cleansing policy which contained additional guidance for decontamination of ultrasound probes. The service carried out transvaginal ultrasound investigations and used individual single use gel probe covers for these procedures. We saw completed daily checklists for ultrasound equipment cleaning had been maintained for 5 machines in clinical use, as well as completed weekly equipment cleaning and checking for the backup ultrasound machine. The daily cleaning checklists were also updated to the service's electronic record systems.

The service had enough suitable equipment to help them to safely care for patients. The service had 6 portable ultrasound units, 5 of which were in use, with one machine identified as a backup in case of need. All equipment units were still under manufacturer's warranty, with repair and breakdown cover arrangements in place. The service had not had any incident of equipment breakdown since it began.

Healthcare assistant staff were provided with supplies of personal protective equipment (PPE) including latex free gloves, masks and aprons, which they would take to clinic locations for booked appointments. The service stored stock items of sundry equipment, including PPE at the main office headquarters.

Requires Improvement

Diagnostic and screening services

The service worked in clinic locations hosted in GP surgeries and other healthcare locations. There were suitable facilities to meet the needs of patients' families.

Staff followed local procedures in GP surgeries and healthcare locations for the safe disposal of clinical waste.

Assessing and responding to patient risk

Staff did not always complete and update risk assessments for each patient and remove or minimise risks. Staff identified and quickly acted upon patients at risk of deterioration

All staff completed basic life support training and were aware of how to respond in case of an emergency.

Administrative staff completed an initial triage of patient referrals according to the service criteria. Any incomplete or inappropriate referrals would be returned to GPs as needed. Sonographers would review and completed further clinical triage of the referral for prioritisation in the service.

Staff did not always know about or deal with any specific risk issues although the service did have criteria for acceptance to the service. The service would not see any patients under the age of 18; any patients with a known cancer site; or any patients who required breast, thyroid or axilla scans. However, the service did not request any pre appointment information regarding any medical conditions' patients may have, and referral information we reviewed contained limited details of any wider health or other risks patients may have had.

We requested details of any patient risk assessments completed by the service. The service provided details of a generic risk assessment which identified risks of slips trips and falls, and risks from contact with spilt chemicals. The service did not identify any specific risk assessments that would be completed for each patient following their referral, however sonographer staff would assess individual referrals based on their clinical judgement.

During our site visit to a clinic setting we saw that staff did not check with patients whether they had any allergies or were allergic to latex. We also saw that staff checked patient ID when patients were in the clinic room already undressed or ready for their procedure.

The service had a process for escalating any urgent findings. If the sonographer identified any untoward findings or concerns at the time of the scan, this would be flagged on the electronic system and followed up by a call to the GP on the same or following day after the findings. The service provided data which confirmed that between March and August 2022 a total of 189 patients had been referred directly back to their GP after the investigation had shown diagnostic concerns.

Staffing

The service had enough staff with the right qualifications, skills, training and experience to keep patients safe from avoidable harm and to provide the right care and treatment. Managers regularly reviewed and adjusted staffing levels and skill mix, and all staff a full induction.

The service had enough sonographers and healthcare assistant staff to keep patients safe. There were 4 sonographers and 4 healthcare assistants who provided clinic appointments at different locations. The service had a clinical lead who at the time of inspection was working 3 half days per week. Staff always worked together at different healthcare locations and there was never any lone working in the service.

Requires Improvement

Diagnostic and screening services

The service had two consultant radiologists who worked on a sessional basis in the service, whose main focus was on quality assurance and review of audit outcomes.

At the service headquarters there was an IT and operations manager, a marketing manager, a reporting manager, and administrative manager. in addition to the clinical lead and the managing director. Within the clinical staff groups there was a healthcare assistant lead and a senior sonographer.

The service had a document check list to complete for employment of permanent members of staff. The service did not use agency staff but had identified a document check list for recruitment of agency staff if needed. This included evidence of CV, right to work in the UK, Disclosure and Barring Service (DBS) checks, two references, evidence of qualifications, and confirmation of registration with a professional body where this applied. From our observations during inspection we saw this guidance was not always followed.

Managers made sure all staff had a full induction and understood the service. Staff were provided with a health and safety handbook and local induction when they joined the service. We were told that any plans for staff recruitment would be dependent on any future increase of service contracts. The service had engaged the services of an independent human resources consultancy for management of staff related matters.

Records

Staff kept detailed records of patients' care and treatment. Records were clear, up-to-date, stored securely but not all information was easily available to all staff providing care.

Patient notes were comprehensive, and all staff could access them easily. The service used an electronic patient record system for all its patient contact and was looking to become entirely paper free from October 2022. All referrals to the service were received from GPs and made via a secure cloud-based digital system. Following initial triage, any referrals not accepted by the service would be returned to GPs, including details of the reasons why the referral was being returned.

The sonographer would review the referral form from the GP on the electronic system. This consisted of a tick box for the type of scan requested and the reason for referral. During the procedure the sonographer would ask the patient for more information about relevant symptoms, such as pain, noting these in the patient's record.

The service had a Picture Archiving and Communication System (PACS) for electronic transfer of scan images. If the sonographer identified any urgent findings or concern following the scan, this would be flagged on the electronic system and followed up by a call to the GP.

The service had a paper consent document which would be completed for any patients having trans-vaginal scans. Staff told us the paper document could not be scanned into the electronic record. Any paper records were collected from site locations at the time of site spot check visits and kept in a file at the services head office.

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Records were stored securely.

Medicines

The service did not prescribe, administer, record or store any medicines.

Requires Improvement

Diagnostic and screening services

Incidents

The service had a process for managing patient safety incidents. Staff recognised incidents and knew how to report them. Managers knew how to investigate incidents and share lessons learned with the whole team and the wider service. However, there had been no incidents reported in the service.

Staff completed training on what incidents to report and how to report them. There were no incidents reported in the service. Staff had a general awareness of incidents in terms of slips, trips and falls, however there was a limited understanding of potential incidents which could affect the service more widely.

Staff knew how to raise concerns and were aware of how to report incidents in line with the service's policy.

The service had no never events.

Staff understood the principles of openness and transparency. The service had a Duty of Candour policy and staff understood the requirement to give a patients and families a full explanation if and when things went wrong.

Staff met during team meetings to discuss feedback and look at improvements to patient care.

Are Diagnostic and screening services effective?

Inspected but not rated

We inspected but do not rate the domain for effective

Evidence-based care and treatment

The service provided care and treatment based on national guidance and evidence-based practice. Managers checked to make sure staff followed guidance.

Staff followed up-to-date policies to plan and deliver care according to best practice. The service identified a broad range of core policies, covering the areas of clinical, corporate, risk management and health and safety, administration, governance, information governance, information management, safeguarding and human resources.

When we reviewed policies during the on-site inspection, we saw each had a start date but did not identify a review date. Also, policies had a front cover sheet with the service name identified for Direct Medicare UK Ltd, however, policies we saw did not always specify the service name in the contents of the policy. Some policies did not appear to be relevant to the service. For example, the service had a repeat prescription policy; however, the service did not prescribe, administer, store or record any medicines. The service also had a Do Not Attempt Resuscitation policy, which would not be relevant for patients attending the service and the types of diagnostic screening procedures provided. During our onsite inspection we saw that the clinical lead was making amendments to policy documents, they told us they were updating the service policies.

Nutrition and hydration

Staff did not always ensure patients had drunk enough water when needed prior to their investigation. Patients could access drinking water at local clinic facilities.

Patients often told us that preparation instructions for different scans was not always clear and we saw some patient appointments were delayed as a result of needing to drink enough water at the time of their appointment.

Patient outcomes

Staff monitored effectiveness in some aspects of care and treatment. They used the findings to make improvements and achieved good outcomes for patients.

The service identified an annual audit plan which included a range of routine service audits. Included in these were audits in the areas of HR induction and training, clinical governance, quality management system, clinical management, business and development, and equipment. The service provided audit results for their cleaning audit and infection prevention and control audits. The environmental cleaning audit for routine office cleaning tasks was comprehensive and complete for each week over the past month.

The service provided details of a template dated 12 January 2022 for completing a room audit risk assessment for clinical rooms. This was a checklist including sections for waste disposal, health and safety, cleaning and cross infection and other areas, including privacy and staff safety. We did not see any completed individual results of this template/ checklist. The service provided two summary documents of infection control audit outcomes entitled infection control March 2022 and infection control September 2021. Within this a different audit template covering various areas of activity, including hand hygiene, decontamination of equipment, cleanliness of room, staff compliance with 'bare below the elbows' during clinic sessions. Again, we did not see any completed individual results of this template/ checklist. The summary stated "*clinical staff were found to be compliant with all aspects of cross infection. Direct Medicare UK Ltd is assured that they are compliant with all aspects of Infection Control. The Staff pay attention to the decontamination of equipment before and after any clinical intervention. Personal Protective Equipment [PPE] [Gloves] are worn for all examinations. The HCA ensured the circumcision examination couch is cleaned after each patient and before the next patient is placed on the bed. The bed is also covered with a disposable cover which is removed and renewed for each patient. All clinic staff strictly adhere to the Direct Medicare UK Ltd dress code ensuring hair is tied back and no jewellery is worn on the hands and wrists. All staff are compliant with the "Bare below the elbows policy". Hand Hygiene policy / procedure observed by all staff.*"

The service provided details of the equipment audit programme. This was an annual checklist of equipment assets and routine maintenance completed. Sonographer staff at clinic locations informed us the ultrasound machine was calibrated in monthly equipment checks at head office, and there was no additional action taken by staff during clinic sessions. We heard conflicting reports form staff about this process.

The service provided details of their clinical action plan, which only identified discrepancy and peer review of ultrasound scans. The service identified topics for an external auditor to compile, including the use of probes; renal and liver pathologies; and gynaecology ultrasound, however the actions were not completed, and the date of completion was indicated as to be confirmed.

The service described how consultant radiologists completed an audit review and discrepancy meetings. We saw results from retrospective reviews undertaken of 25 patient scans, completed for each of the 4sonographers between January to June 2021. The review identified actions for the sonographer, including scanning and training sessions with a senior sonographer to improve advanced scanning techniques and reporting skills. All the scan reviews were graded as being of excellent standard with minimal errors of exposure imaging and diagnosis.

The service provided reports of scan investigations to the referring GP in a timely way within 24-48 hours after scans, although we did not see evidence of any monitoring for this.

Managers shared information from the audits during staff meetings.

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 development.

Staff were experienced, qualified and had the right skills and knowledge to meet the needs of patients. The service's recruitment policy stated references and original qualifications for staff would be verified and records we reviewed confirmed this.

Managers gave all new staff a full induction tailored to their role before they started work. The service issued every new staff member with an employee health and safety handbook, and provided a local induction, with a checklist for recording this.

Managers supported staff to develop through yearly, constructive appraisals of their work. Senior sonographers completed competency assessments for sonographers in different ultrasound techniques. The service provided details of the sonographer competency checks that had been completed between August and December 2021. All of these concluded that staff were competent to undertake general abdominal ultrasound scanning and to work unsupervised in the service. One of the forms, although appearing to be the same template document, referenced the name of a different service provider.

The service provided details of competencies to be completed by the 4healthcare assistant staff. The 'competency evaluation form' identified a grading score from 1-5 for assessing staff's performance. An overall total of 18 areas were identified for assessment, these included subjects such as use of PPE, decontamination of equipment, communication skills, control of documents, and confidentiality. We saw records for 4 staff completed between December 2019 and December 2021, which indicated staff had completed these and were all assessed as proficient for all areas.

Managers made sure staff attended team meetings or had access to full notes when they could not attend.

Managers identified any training needs their staff had and gave them the time and opportunity to develop their skills and knowledge.

Staff had the opportunity to discuss training needs with their line manager and were supported to develop their skills and knowledge.

Multidisciplinary working

Doctors, sonographers and healthcare professionals worked together as a team to benefit patients. They supported each other to provide good care.

Staff held regular meetings to discuss patients and improve their care. The service had key relationships with GPs who made referrals to the service, and other professionals at the host NHS healthcare clinic premises. Staff also followed systems for raising any urgent concerns, whenever this was needed.

Seven-day services

Key services were available to support timely patient care.

Services were mostly available Monday to Friday across different clinic locations, between 8.30 am and 5 pm. In some locations, clinics were available on Saturday mornings, dependent on local facilities and contractual agreements.

Consent, Mental Capacity Act and Deprivation of Liberty Safeguards

Staff did not always support patients to make informed decisions about their care and treatment. They did not always follow national guidance to gain patients' consent. They did not always know how to support patients who lacked capacity to make their own decisions or were experiencing mental ill health.

Staff did not always understand how and when to assess whether a patient had the capacity to make decisions about their care. Staff did not always gain consent from patients for their care and treatment in line with legislation and guidance. Although the provider had a consent form, this appeared to be in a generalised form and not specific to the providers context.

For example, we saw that the provider's consent policy included a patient consent form. The consent form stated *"completion of the form must be commenced at the first outpatient visit that a decision to treat is made. This must include name of procedure/treatment (and brief explanation) the intended benefits, and serious/frequently occurring risks. Judgement should not be made about whether to give information, to allow the patient to make an informed judgement. It is permitted to add or delete parts of any text. It is also best practice to document additional information/discussion in the case notes. You sign the form, print your name, date, and job title."*

However, there was no clear process for staff to follow which reflected this policy guidance and in practice we did not see staff maintaining a consistent approach for patient consent. The provider did not have a procedure for ensuring that consent for the investigation was obtained and documented at the first contact with the service, and prior to the appointment booking. We were told that 'in practice the service relied on patients' indication of their consent, by patients' attendance at the appointment.

Staff did not always make sure patients consented to treatment based on all the information available. The provider's consent policy stated *"Please give the appropriate information leaflets and use as a base for discussion. As the information leaflet is designed for a wide population, it may include aspects that do not apply to your particular patient."* We did not see any evidence of information leaflets for the specific ultrasound invest investigations being provided to or discussed with patients. The service's consent policy included details of a patient consent proforma. Guidelines for completion of the consent form stated that *"completion of the form must be commenced at the first outpatient visit at a decision to treat is made*". However, staff did not always clearly record consent in the patients' records. We were told that the service only requested written consent for patients who were having transvaginal scans. We spoke to three patients who had undergone a transvaginal scan, of whom two had said they had received and responded to a text message asking for their consent to the scan, but none said they had completed a written consent form. For patients who could not access the text message consent platform, a written consent document would be completed. However, this was not scanned or uploaded to the electronic patient record.

Additionally, since the service had an electronic record system and was developing towards becoming paper free, there was no mechanism for any consent form to be added into the electronic patient record. Of ten patient records we reviewed at the service headquarters, we saw that verbal consent was documented on 3records; text message consent was recorded on 4 patient records, and no record of consent was documented on the electronic records system for 3 patients. Additionally, we spoke with 1 patient who had discussed information only at the time of their scan appointment and had provided informed consent. For 3 patients who were due to have transvaginal scans, two had been asked for consent by text message and one had been asked to sign written consent; the third patient could not recall havening been requested to provide their consent at all. We saw during a site visit to a clinic that the service sent

patients a text message requesting them to provide consent for their procedure, only at the time of their appointment. We also saw that patient identity was only checked by the sonographer once the patient was undressed and on the couch. This was because the healthcare assistant manually entered the name and date of birth details into the ultrasound machine and the sonographer then reads it off the machine. This did not adhere to the Society of Radiographers guidelines which state three questions should be confirmed prior to the procedure, including address or patient hospital number as well as full name and date of birth.

Staff completed online training and had a general awareness of the Mental Capacity Act. Staff could describe and knew how to access policy on Mental Capacity Act. However, staff did not describe in practice how they would manage consent processes where there were any concerns about patients who may lack capacity to give informed consent, or who were experiencing mental ill health.

Are Diagnostic and screening services caring?

Good

We rated caring as good.

Compassionate care

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

Staff were discreet and responsive when caring for patients. Staff took time to interact with patients and those close to them in a respectful and considerate way, although at times the clinic appointment could be very fast paced. We saw that staff spoke with patients in a sensitive way.

Patients we spoke with said staff treated them well and with kindness, although we heard isolated concerns from some patients who said they felt rushed during appointments they had attended in the service. Other patients said they felt a little unhappy with staff attitude at times, some felt staff spoke to them in an overly familiar way using expressions such as ‘dear’ and ‘are you comfortable darling’.

Staff followed policy to keep patient care and treatment confidential. Staff respected patients’ privacy when they were preparing for their procedure.

Staff understood and respected the individual needs of each patient and showed understanding.

Staff understood and respected the personal, cultural, and social needs of patients and how they may relate to care needs.

Emotional support

Staff provided emotional support to patients, families and carers. They understood patients' personal and cultural needs.

Requires Improvement

Diagnostic and screening services

Staff gave patients and those close to them help and emotional support when they needed it. Patients we spoke with mostly said they did not feel any need for emotional support as the appointment was for a limited time and a short procedure. However, patients were made to feel comfortable and felt reassured by staff. We observed staff speaking softly to encourage and reassure patients during their procedure, particularly if they appeared anxious.

During our site visit, most patients we spoke with said they had not received detailed information about their scan investigation prior to their appointment. Most patients said they had received text message confirmation of the appointment, although this was often the day before, or if they had requested this from the service.

Staff supported patients and helped them maintain their privacy and dignity.

Staff understood the emotional and social impact that a person's care the service had on their wellbeing and on those close to them. However, the limited time for each procedure meant that there was only a short time for staff to interact with patients. We observed that staff often appeared to be rushed when delivering care.

Understanding and involvement of patients and those close to them

Staff supported patients, families and carers to make decisions about their care and treatment.

Staff made sure patients and those close to them understood their care and treatment, within the limited time for face to face communication at the time of their appointment.

Staff talked with patients, families and carers in a way they could understand. Staff were unable to tell us if there was any specialist support provided for patients who required communication aids.

Patients and their families could give feedback on the service and their treatment and staff supported them to do this. The sonographer informed all patients they would receive a patient feedback form to complete after their appointment. Patients said they had received a feedback form from the service.

Staff supported patients to make informed decisions about their care.

Patients gave positive feedback about the service. Patients particularly appreciated the responsiveness of the service and the timeliness of booking appointments, although other patients said that the instructions and communications in the appointment booking system were not always easy to follow.

Are Diagnostic and screening services responsive?

Requires Improvement

We rated responsive as requires improvement.

Service delivery to meet the needs of local people

The service planned and provided care however this was not always in a way that met the needs of local people and the communities served. It worked with others in the wider system and local organisations to plan care.

Requires Improvement

Diagnostic and screening services

Managers planned and organised services, so they met the changing needs of the local population. The service offered different types of ultrasound investigations, in response to GP referrals.

The service was provided at different locations, hosted within GP and healthcare clinic facilities, to provide local access and ensure the required staff were available for patients.

Facilities and premises were appropriate for the services being delivered. Patients booked in at the main reception and were directed to a relevant waiting area for the service. Patients had access to drinking water from within the local healthcare setting.

However, during our site visit to locations, we heard from many patients that instructions for scan preparation were not always clear or communicated in a timely way. Five of six patients we spoke with had reported problems with the instructions for scan preparation. One of these patients said they had received a phone call at 9.27am when their appointment was at 10am, asking if they could change their appointment to the afternoon. They said they could not do this, and it was only at this point the patient became aware that they needed to drink before the procedure. Written details sent to the same patient only stated that they were to attend for a scan, it did not state what scan they were having and did not include any information of the preparation required. Another patient reported they had received a text message 40 minutes before the appointment telling them not to have anything to eat for 6 hours before the appointment, but unfortunately, they had already eaten by the time he received this message. A third patient informed us it was their second scan and they had been referred for two different scans. They had received a generic text message, which did not clearly identify which scan they were having. They had not received any instructions about the need to drink water before the procedure and at the time of their appointment had to wait 40 minutes to enable them to drink more water. The scan proceeded but the patient was told it was inadequate and would need to be repeated. Following the inspection, the service provided details of a standardised letter which would be sent to patients when their appointment was confirmed. Whilst this did give clear instructions about preparation for the scan, most patients we spoke with did not clearly receive this information

Managers monitored and took action to minimise missed appointments. Managers reviewed the electronic referral system to ensure patients had their appointments booked within target response times.

Managers ensured that patients who did not attend appointments were contacted. If any patient missed two appointments, the service would refer the patient back to their GP.

The service supported the NHS in overall provision for diagnostic investigations, helping to relieve the pressure on NHS clinical services.

Clinics were routinely provided Monday to Friday 8.30am -5.00pm. Occasional clinics on Saturday mornings were available at some locations.

Meeting people's individual needs

The service did not always take account of patients' individual needs and preferences. Staff did not always make reasonable adjustments to help patients access services.

Staff had some awareness of the support needs of patients living with learning disabilities and the service had a policy on meeting the needs of patients with a disability or sensory loss. When we spoke with staff however, we found there was limited experience and application of this knowledge in practice.

Requires Improvement

Diagnostic and screening services

The service did not provide any information leaflets, and these were not available in languages spoken by the patients and local community. At the time of our inspection, the service's website was not available due to this being upgraded. Following the inspection, we saw the service's website provided a list of the different types of scan available, however there was no specific details about any of the procedures, or whether any preparation would be required. Information was not available in other languages for patients whose first language was not English and who may have needed this.

Managers told us that staff, and patients, loved ones and carers could get help from interpreters or signers when needed. However, the service did not identify a policy for this provision and staff could not describe any clear examples of how this support would be accessed.

We observed during our site visit that there was a rapid turnaround time for clinic appointments, which limited the opportunity for any questions or discussions patients may want to raise. There sometimes appeared to be a hurried engagement with patients where the focus was on the speed of completing the appointment within time.

Access and flow

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

Managers monitored waiting times and made sure patients could access services when needed and received treatment within agreed timeframes. Patients had a choice of appointments. During our site visit we saw that clinic appointments were kept to time during a very busy schedule.

Scan reports were prepared and available for referring GPs within seven days. Urgent reports were communicated to GPs within 24 hours, where any concerns were identified.

Managers worked to keep the number of cancelled appointments to a minimum.

When patients had their appointments cancelled at the last minute, managers made sure they were rearranged as soon as possible.

Learning from complaints and concerns

It was not always easy for people to give feedback and raise concerns about care received. The service had a process to review any concerns and complaints.

Patients, relatives and carers did not always know how to complain or raise concerns.

The service's website had a link to information about how to raise a concern titled '*DMC Guide to Submitting Complaints and Concerns'*. Following the inspection, we saw the website link was broken. Patients we spoke with said they had not been provided any information about how to raise a concern or make a complaint.

The service had a policy on complaints, however clinical staff's awareness of this was brief. The service had received no complaints, although managers had a process for reviewing any issues or concerns raised in patient feedback.

Managers shared patient feedback with staff, and we saw meeting minutes noting where any learning was discussed to identify improvements in the service.

Requires Improvement

Diagnostic and screening services

Are Diagnostic and screening services well-led?

Requires Improvement

We rated well led as requires improvement.

Leadership

Leaders did not always have the skills and abilities to run the service. They did not always understand and manage the priorities and issues the service faced. They were visible and approachable in the service for staff. They mostly supported staff to develop their skills.

There was no registered manager in the service at the time of inspection. The nominated individual was the chief executive of the company, who worked full time in the service. Their main responsibility was human resources, recruitment and finance, with support from an external HR consultancy, in contract arrangements. The chief executive had a background in the field of psychology prior to the establishment of Direct Medicare UK Ltd. The service had an organisational structure, with a clinical manager, reporting manager, marketing manager and administrative manager who were mostly based at the service headquarters. The operations manager and marketing manager also conducted site visits to different locations periodically. There was a healthcare assistant lead and senior sonographer identified within the clinical services.

The clinical manager had been the registered manager since the original provider registration in June 2019. However, the clinical manager had cancelled their registered manager status in February 2021 after leaving the service and had only recently returned to Direct Medicare UK The clinical manager had responsibility for policies and procedures across the service, with broad oversight of quality management, including governance, complaints, risk management, audit, and safeguarding. They were only working in the service for three half days per week at the time of inspection, and although we heard there was an intention for extending this, there were no clear plans timescales for when the clinical manager would become more fully available in the service. We had concerns regarding how the clinical manager would be able to effectively fulfil the wide responsibilities of their role, including key areas such as governance and quality, given their limited working hours.

One of the directors was identified with key responsibilities including as the accountable emergency officer; Mental Capacity and Liberty Protection Safeguards Lead and Caldicot Guardian. However, they had full-time working commitments outside of the service and therefore limited capacity for delivering these responsibilities within Direct Medicare UK Limited

Leaders did not always understand the challenges to quality and sustainability in the service. There was a broad ambition to grow the business but there were no clear plans identifying actions to achieve this or timescales for completion. The chief executive told us that it is very safe for patients and there were policies in place which staff can access. However, there was little further detail of how leaders had assurance or effective systems for continued monitoring and quality measurement in the service, or succession planning for the future expansion of services.

Vision and Strategy

The service did not have a clear strategy for turning their vision into action, developed with all relevant stakeholders. The vision was aligned to local plans within the wider health economy. Leaders and staff understood and knew how to apply them but did not monitor progress.

Requires Improvement

Diagnostic and screening services

The chief executive told us the service did not have a written strategy but a mission statement saying services were 'fast reliable and accurate'. Leaders and staff told us patient focus was a central aim of the service, with a gradual plan to extend services, dependent on new contracts. At the time of inspection, the service was preparing to apply for a new contract from the NHS. Office based staff were aware of the service's broad aims and were involved in some of this planning and related discussion.

The service included details of their vision within existing NHS contracts as *'Medicare's vision is to respond to the growing needs and demands for provision of comprehensive range of services serving patients in community and primary health care settings. Our aims include being able to help patients have quick and accurate diagnosis and treatment for their presenting conditions, and thus aid their quick recovery and treatment management plans. In so doing, patients can avoid the long waits and inconvenience of needing to travel to hospital settings for their routine investigations.'*

The service also described their intention to deliver services at local GP sites, including outside normal working hours for patients, with particular focus on 'those with "special needs" who may have difficulty travelling and who will derive the greatest benefit.' However, during the inspection we did not hear of any direct initiatives to indicate how patients who had any additional needs would be identified, or their individual needs responded to appropriately.

Following the inspection, the service provided details of a vision statement, which listed 'Vision and Values' as 'Valuing People; Listening to and respecting the public, patients' communities and staff; Working Together; To deliver the right care, in the right place at the right time; Innovation; Creating the culture and environment that inspires and supports good ideas; Quality; Striving for the best possible care to achieve the best outcomes; Investing Responsibly; Making the right decisions for the best value, affordable healthcare.' The vision and values document expressed six generalised strategic objectives which appeared to be based on a standardised template format. There was no clarity or detail of any actions to achieve the general strategic objectives and staff, including the chief executive, appeared largely unaware of this document and its contents.

Following the inspection, the service also provided details of their business plan which set out the objectives as:

1. To ensure that individual roles and responsibilities within the organisation, relating to clinical audit and research if appropriate are clear.

2. To outline the governance arrangements through which the quality of audit activity will be monitored, and appropriate dissemination of outcomes take place.

3. To summarise the audit priorities of Direct Medicare UK Ltd.

4. To promote patient and public involvement in clinical audit, in order to ensure opportunities for capturing feedback from patient experiences and wider public views are optimised.

5. To outline the training and support available for staff participating in audit and the mechanisms through which audit capability will be developed within the workforce.

6. Increase training opportunities that would promote clinical effectiveness.

7. To identify and protect innovation and intellectual property.

However, these objectives were different from those identified in the values document and again staff including the chief executive, were mostly unaware and not engaged in this area of development.

The service leaders appeared to work in isolation, with an apparently inconsistent and disjointed approach to strategy development in which staff were not fully included.

Culture

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

Staff we spoke with said they felt supported and valued. There was a positive culture in the service which centred on the needs of patients, with an open and friendly aspect in everyday staff communications. The service had the feeling of close family relationships, particularly in the shared open- plan space of the head office. There was a freedom to speak up policy with an identified lead for staff to raise any concerns to, should these arise. There had been no reports of freedom to speak up concerns from any staff.

Staff we spoke with said they had opportunities for development, including requests for attendance at specialist conferences. Managers met regularly with staff, both in groups and individual meetings. We saw from staff meeting minutes that managers were open in their discussions with staff, encouraging professional and effective communications, and support for other team members. The service had a focus on staff wellbeing and enabled individual staff to engage and contribute their ideas for service improvements. Staff worked collaboratively and had pride in working for the service.

Governance

Leaders did not always operate effective governance processes, throughout the service and with partner organisations. Staff at all levels were mostly clear about their roles and accountabilities and had regular opportunities to meet, discuss and learn from the performance of the service.

We saw during the inspection that recruitment procedures were not followed according to the service's policy. This did not meet the requirements of Schedule 3 Health and Social Care Act 2008 (Regulated Activities) Regulations 2014.

The service held monthly quality meetings with leaders from local NHS commissioners for routine monitoring of key performance indicators, for the commissioned services being delivered at different sites under contractual arrangements. The service also held monthly governance meetings and clinical governance meetings, although there was some confusion between the different meetings. We saw from the meeting notes provided by the service that the monthly governance meetings held in the service had variable content and did not always follow a standardised agenda. The service initially provided records of the governance meetings held over dates in May, June and July 2022. These appeared to be mostly related to a document heading of 'clinical competency points', and criteria for specific ultrasound procedures, incorporating a list of clinical measures. Overall, these records appeared to relate to a training session and a clinical discussion context and did not reference any systems for oversight of quality and safety in the service. There was no reference to service activity, audit performance or review of outcome measures identified.

The provider later provided a record of a clinical governance meeting held in February 2022, which was identified as the initial clinical governance meeting in the service. The meeting agenda appeared as a different format and was noted as being a standardised agenda for clinical governance meetings. This agenda included items for supervision update; discrepancies; audit; protocols update; ultrasound machines; safeguarding; policies; training; and additional items. Key

actions were identified under each item, including for example 'competency levels to be documented with reference to supervision sessions; audit plan to be implemented; sonographers to update safeguarding training to level 3'. Although this document identified who was responsible for the actions to be completed, there was no indication of timescales for completion and we saw no further evidence, or these being reviewed as completed.

For either of these meeting records there were no related specific action plans to identify any monitoring processes or improvement outcomes to be achieved.

We also saw there was a lack of effective auditing of consent processes

We also observed that although the service identified several relevant audits, there was no overall indication of how quality improvement across the service would be delivered in the future. The service's business plan made reference to broad objectives, including '*To outline the governance arrangements through which the quality of audit activity will be monitored and appropriate dissemination of outcomes take place,*' and '*To promote patient and public involvement in clinical audit, in order to ensure opportunities for capturing feedback from patient experiences and wider public views are optimised.*' However, there was no further detail or clarity of what specific actions would be needed towards achieving this, or any related timescales and monitoring processes to support this.

Staff in the service were mostly clear about their roles and responsibilities, although there was some overlap of key functions for senior leaders, including in key areas such as for safeguarding leadership.

The service held monthly staff meetings for all staff to attend. Meeting minutes showed staff discussed key areas of the service, including clinic details, feedback from site clinic visits by senior leaders, clinical issues, and an update from the chief executive.

Management of risk, issues and performance

Leaders and teams had some systems to manage performance although there was some duplication in these. They identified some relevant risks and identified actions to reduce their impact, but there was an overall lack of corporate oversight in risk management. They had plans to cope with unexpected events.

The service had identified a leadership structure and a governance process for staff to follow. However, governance processes were unclear and did not enable effective monitoring of key service information. There was some duplication with systems and risks were not always identified or reviewed.

The service provided routine monthly reports to NHS commissioners to demonstrate outcomes against key performance indicators (KPIs). Although we saw that the service met all the required KPIs for contracts being delivered, the service did not manage any risks where patients had their scans deferred after having received poor information.

We saw during inspection there was a lack of patient specific risk assessments identified but generalised risk assessments were such as environmental hazards completed. Similarly, at an organisational level, there was a lack of corporate oversight of risk, and systems to identify, or reduce known risks were not always effectively managed. During the inspection, operational leaders told us the service had a risk register which was reviewed in monthly governance meetings, however governance meeting minutes we reviewed did not reflect this. Following inspection, the service provided details of their risk register which identified twelve separate risk items. The risks items described a diverse range of potential risks, such as 'IT failure'; ' member of staff to report sickness to operational manager before 8am'; ' liabilities for Public and Employees and Corporate Insurance' and ' Risk of infection due to lack of hand washing'. Mitigating actions were described for each risk, many of which had been completed, however for 11 out of the 12 risks

documented there was a continuing review date of 'July 2023'. The operations manager was identified as the risk owner and risk handler for all of the risks documented. Alongside the risk register document was the corporate risk register which was documented in a different format and identified seven corporate risks. There was overlap of several items between the corporate risk register and the service risk register, including staff training/ induction; loss of IT. The risk owner was identified by staff's management role, however there were no timescales documented, and again we saw no reference to any review of the risk register or corporate risk registers in governance meeting minutes. During our interview with the chief executive, they described having no risks in the service, and appeared unaware of either of the risk register documents.

The service had a business continuity and disaster recovery plan, and actions were identified in case of IT or equipment failure.

Information Management

The service collected data and analysed it. Staff could find the data they needed, in easily accessible formats, to understand performance, make decisions and improvements. The information systems were integrated and secure.

The service had developed comprehensive digital systems for managing patient referrals, overall service activities, and staff matters. The service had access to timely reports in a range of areas, including overall performance, service demand and patient outcomes. We saw staff reviewed different types of data in the service's meetings, using this to develop improvements.

The service was working towards the ISO9001 standard for quality management systems and was aiming to become 'paper free' in October 2022.

Engagement

Leaders and staff actively and openly engaged with patients and staff to plan and manage services.

The service held regular staff meetings where staff could participate and contribute their views about any improvements to make. We saw that staff meetings were formally documented with standing agenda items for discussion. Leaders encouraged staff to actively make suggestions on all aspects of the service.

Patients were invited to complete a feedback form after their appointment, we saw that staff reviewed and discussed any patient feedback received.

Learning, continuous improvement and innovation

All staff were committed to improving services. There was a limited focus on quality improvement methods, innovation and participation in research.

The service had a broad aim to make improvements wherever these were identified. However, we did not see there was a focused approach to quality improvement and continuous learning. The service's business plan stated a broad aspiration to '*to promote high quality audit and research*' and *'to increase training opportunities that would promote clinical effectiveness',* however we did not see any details of how this would be achieved, or any evidence of progress in this area.

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 11 HSCA (RA) Regulations 2014 Need for consent Staff did not always follow national guidance and service policies for obtaining and documenting patients' consent.

Regulated activity	Regulation
Diagnostic and screening procedures	Regulation 17 HSCA (RA) Regulations 2014 Good governance Leaders did not always understand and manage the priorities in the service. Governance systems were unclear and there was a lack of corporate oversight in management of risks and issues across the service.