

Bodyscan W1

Quality Report

49 Marylebone High Street,
London
W1U 5HJ
Tel: 020 3490 4171
Website: www.bodyscanuk.com

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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

Bodyscan W1 is operated by Bodyscan Limited. The service provides a diagnostic imaging service to adults only. We inspected this service using our comprehensive inspection methodology. We carried out the unannounced inspection on the 19th February 2019

The service uses a dual energy X-ray absorptiometry (DEXA) scanner to measure body composition and provide patients with an indication of their levels of fat and bone density. The facility is operated out of one room rented from another independent health provider which used the DEXA scanner to carry out bone density testing.

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 that service as **requires improvement** overall.

However:

- The lack of record keeping verifying clients, their medical conditions and proper verification of identity plus results of scans as well as lack of records authorising scans by a registered clinician laid the process open to the risk of inappropriate and time inappropriate scans being undertaken. The lack of individual contemporaneous client records containing all of this information in one place was in breach of HSCA Regulation 17 (2) (c).
- There were no prior medical referrals of clients to this service. There were doubts over the availability of the registered clinician/referral assessor having the time capacity to review and authorise all scans before they were undertaken.
- We saw no evidence or records to show that the registered clinician/referral assessor had approved

all scans before they were undertaken. For the protection of the client and for the protection of the scanning operator, the requirements for informed consent were not being met.

- Guidance which treatment was based on was not formally reviewed to ensure it remained up to date.
- The services' complaints documentation referred patients who were dissatisfied with the outcome of their complaint to the Local Government Ombudsman. The correct body for patients to refer to is the Independent Healthcare Sector Complaints Adjudication Service (ISCAS).
- Policies did not have review dates so it was not clear when they would expire.
- There was no lone working policy assessing and mitigating risk to staff working alone
However:
 - The service provided mandatory training in key skills to all staff and made sure everyone completed it.
 - Staff understood how to protect patients from abuse and harm. Staff had training on how to recognise and report safeguarding concerns and they knew how to apply it. There was a clear safeguarding policy in place.
 - The service controlled the risk of infection and there was a clean clinical environment with the right equipment in place.
 - The manager demonstrated that when things went wrong, patients were apologised to and the service used the incident as an opportunity to learn and improve.
- Patients had their needs around nutrition, hydration and pain management taken care of.
- Service staff with different areas of expertise worked together to improve the service.
- Patients were cared for with sensitivity and compassion

Summary of findings

- Patients' privacy and dignity was respected at all times.
- Staff had a good understanding of the emotional impact of body composition reporting and were sensitive to the vulnerabilities and requirements patients visiting the service might have.
- Staff answered patients' questions about the scanning process and the details of their body composition reports
- The service was planned and delivered in a way which met the needs of patients.
- Information was provided to patients prior to their appointment which included what to expect, how to find the service and that fasting as required.
- Patients could access the service promptly at a time which suited them. Patients were able to choose appointments through the service's website where all bookings were made. The service were always able to see patients within three days. There were no waiting times.
- Themes from complaints and patient concerns raised informally were discussed between staff and used to ensure the service improved.
- Staff we spoke with were highly positive about working for the service and said the manager was personable and approachable. Staff told us they felt supported and valued.
- Staff and the manager of the service we spoke with described a positive working culture where staff worked collaboratively and with a common purpose to improve the service and care for patients.
- The manager we spoke with described promoting a culture of learning and improvement through regular communication with staff and monitoring of the service.
- Risks to the service were identified and mitigated.
- The service had a comprehensive list of policies and procedures which staff could refer to inform their work.

Nigel Acheson

Deputy Chief Inspector of Hospitals

Summary of findings

Our judgements about each of the main services

Service

Diagnostic imaging

Rating

Requires improvement



Summary of each main service

Bone density and body mass scans was the main activity of the provider.

We rated this service as requires improvement because it was safe, effective, caring, responsive and well-led.

Summary of findings

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Requires improvement 

Bodyscan W1

Services we looked at

Diagnostic imaging

Summary of this inspection

Background to Bodyscan W1

Bodyscan W1 is operated by Bodyscan Limited. The service opened in 2015. It is a private service in central London. The service rents a room and scanner from another service and was situated within that service's clinic. Maintenance of the equipment and infrastructure of the room was managed by the host clinic. The service accepts bookings online and patients are self-funded.

The service has had a registered manager in post since 2016. The service is registered to provide diagnostic and screening services to adults. This is the first time that we have inspected this location.

Our inspection team

The inspection was undertaken by a CQC lead inspector. The inspection was overseen by Terri Salt, Head of Hospital Inspection.

Information about Bodyscan W1

The service operates out of one room and is registered to provide the following regulated activities:

- Diagnostic and screening services

During the inspection, we inspected the room within which the service operates and the waiting area which is shared with another service. We spoke with two members of staff including the staff member who facilitates the consultation and the service manager. We spoke with two patients.

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 was the service's first inspection since registration with CQC.

Activity (February 2018 to February 2019)

- In the reporting period February 2018 to February 2019 there were 1357 scans carried out. 100% of these were self-funded

One Bodyscan staff member worked at the service with occasional cover from one other operator. The service was managed by the sole director of the company who was also the registered manager.

Track record on safety

- 0 never events
- 0 clinical incidents
- 0 serious injuries

0 incidences of hospital acquired Meticillin-resistant Staphylococcus aureus (MRSA),

0 incidences of hospital acquired Meticillin-sensitive staphylococcus aureus (MSSA)

0 incidences of hospital acquired Clostridium difficile (c.diff)

0 incidences of hospital acquired E-Coli

1 complaint relating to a missed appointment

The service contracted cleaning and infrastructure services as well as maintenance of the DEXA scanner from its host clinic.

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 lack of record keeping verifying clients, their medical conditions and proper verification of identity as well as lack of records authorising scans by a registered clinician laid the process open to inappropriate and time inappropriate scans being undertaken. The lack of individual contemporaneous client records containing all of this information in one place was in breach of HSCA Regulation 17 (2) (c).
- There were doubts over the availability of the registered clinician/referral assessor having the time capacity to review and authorise all scans before they were undertaken.

However:

- The service provided mandatory training in key skills to all staff and made sure everyone completed it.
- Staff understood how to protect patients from abuse and harm. Staff had training on how to recognise and report safeguarding concerns and they knew how to apply it. There was a clear safeguarding policy in place.
- The service controlled the risk of infection and there was a clean clinical environment with the right equipment in place.
- The service managed radiation safely and had a radiation protection advisor in place.
- The manager demonstrated that when things went wrong, patients were apologised to and the service used the incident as an opportunity to learn and improve.

Requires improvement



Are services effective?

We do not rate this question for diagnostic imaging services.

- Treatment was based on national guidance and best practice.
- Patients had their needs around nutrition, hydration and pain management taken care of.
- Service staff with different areas of expertise worked together to improve the service.
- Guidance which treatment was based on was not formally reviewed to ensure it remained up to date.

Are services caring?

We rated caring as good because:

- Patients were cared for with sensitivity and compassion.

Good



Summary of this inspection

- Patients' privacy and dignity was respected at all times.
- Staff had a good understanding of the emotional impact of body composition reporting and were sensitive to the vulnerabilities and requirements patients visiting the service might have.
- Staff answered patients' questions about the scanning process and the details of their body composition reports.

Are services responsive?

We rated responsive as good because:

- The service was planned and delivered in a way which met the needs of patients.
- Information was provided to patients prior to their appointment which included what to expect, how to find the service and what fasting as required.
- Patients could access the service promptly at a time which suited them. Patients were able to choose appointments through the service's website where all bookings were made. The service were always able to see patients within three days. There were no waiting times.
- Themes from complaints and patient concerns raised informally were discussed between staff and used to ensure the service improved.

However:

- The services' complaints documentation referred patients who were dissatisfied with the outcome of their complaint to the Local Government Ombudsman. The correct body for patients to refer to is the Independent Healthcare Sector Complaints Adjudication Service (ISCAS).

Good



Are services well-led?

We rated well-led as requires improvement because:

- There were deficiencies in record keeping.
- There was a lack of good governance in relation to the authorisation of scans, pre-scan and the lack of processes to ensure informed consent.
- Risks we highlighted as a result of our inspection were not included in the provider's risk register.

However:

- Staff we spoke with were highly positive about working for the service and said the manager was personable and approachable. Staff told us they felt supported and valued.

Requires improvement



Summary of this inspection

- Staff and the manager of the service we spoke with described a positive working culture where staff worked collaboratively and with a common purpose to improve the service and care for patients.
- The manager we spoke with described promoting a culture of learning and improvement through regular communication with staff and monitoring of the service.
- Risks to the service were identified and mitigated.
- The service had a comprehensive list of policies and procedures which staff could refer to inform their work.





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 outpatients and diagnostic imaging services safe?

Requires improvement 

We rated safe as **requires improvement**.

Mandatory training

- **The service provided mandatory and statutory training in key skills to all staff and made sure everyone completed it.**
- Data provided by the service showed that all staff were fully compliant with all statutory and mandatory training modules with the exception of basic life-saving, which only one out of three staff had completed. At the time of inspection the remaining two staff were booked onto this training.
- Statutory training modules included Ionising Radiation Medical Exposure Regulations (IRMER) operator training and theory. Mandatory training included safeguarding vulnerable adults, data protection, basic life life-saving, Bodyscan DEXA competence and equality and diversity in social care.

Safeguarding

- **Staff understood how to protect patients from abuse and harm. Staff had training on how to recognise and report safeguarding concerns and they knew how to apply it. There was a clear safeguarding policy in place.**
- Staff we spoke with on inspection demonstrated a good awareness of the need to identify patients at risk of harm who could use the service, such as those with

eating disorders. Staff told us that where they had had patients they were concerned about they had signposted them to appropriate services for further support.

- All staff had been trained in safeguarding adults level 1. The service did not see patients under the age of 18. There was a safeguarding lead in place who was the service manager.

Cleanliness, infection control and hygiene

- **The service controlled infection risk well.**
- Staff observed infection prevention and control measures to prevent the spread of infection, and kept equipment and the premises clean. The clinic which rented the room to Bodyscan were responsible for cleaning the treatment room. Staff we spoke with told us that the room was usually well-cleaned but they raised with the service when cleanliness issues arose and these were always rectified.
- The service did not undertake any invasive or intimate procedures. However staff were aware of the need to limit the risk of infection by washing their hands and cleaning equipment. There was antibacterial hand gel available in the clinic and the scanner was wiped clean with disinfectant wipes after each use.
- There was an infection control policy in place which staff could access. This policy set out the procedures and expectations of the service in relation to cleanliness and infection control. There had been no healthcare acquired infections in the 12 months prior to inspection.

Diagnostic imaging

- The room which which the service used was brightly lit, visibly clean and clear of trip hazards. There was an information sheet on the wall describing the service's bare below the elbows procedure. Staff we observed were bare below the elbows.

Environment and equipment

- The design, maintenance and use of facilities, premises and equipment kept people safe.
- The service had a suitable environment and the right equipment and these were managed in a way which kept patients safe.
- Bodyscan W1 rented a room containing a dual energy x-ray absorptiometry (DEXA) scanner from the clinic in which the service was situated. The scanner was under a lifetime warranty from the supplier and annual maintenance was carried out. There was a radiation protection supervisor who was also the service manager and a radiation protection supervisor.
- The DEXA scanner at Bodyscan W1 was calibrated to the equivalent scanner at Bodyscan's other site in London, which ensured that patients received accurate reports which they could compare accurately to track their progress.
- The scanner was under a lifetime warranty from the supplier and preventative maintenance was carried out every six months. For the DEXA scanner to work, staff also had to perform several quality control checks to calibrate the equipment. We were told that occasionally the quality control checks might fail on the first attempt, and this. The scanner passed its checks on the second attempt however if the scanner did not pass on the second attempt, then the service had to cancel clients for that day and send them to the other Bodyscan location if necessary.

Assessing and responding to patient risk

- Staff completed and updated risk assessments for each client and removed or minimised risks.
- As the type of scanner used by the service issues a low dose of ionizing radiation, the staff member facilitating the scan stayed in the room with the patient and sat behind a radiation safety screen during the exposure.

Access to the room where scans were carried out was restricted. The door to the room was locked during scans and there was a 'no entry' sign on the door indicating that there was radiation.

- There was a radiation protection advisor (RPA) available through the clinic within which the service was situated. The service also had their own RPA monitoring both sites where the service operated.
- Clients initiated the referral procedure by booking online. There was no prior medical referral process by the client's GP. The process included a check by a qualified clinician – a referral assessor – against set referral criteria. These criteria were contained in Bodyscan's referral protocol, including: clients were 18 years of age and older, were not pregnant, and were under 190 kilograms in weight because of the weight restriction of the scanning table that clients would lie on. Clients with implants or pacemakers were able to use the scanner. Clients were given clear instructions on physical measures they needed to take before the scan took place.
- Managers and staff we spoke with were aware of the need to escalate unexpected or concerning findings on the scans, although there was no formalised process for doing this. Staff we spoke with described an incident where they had, with the patient's permission, discussed an unusual scan with a GP who worked in the clinic where the service was situated and as a result, advised the patient to seek further tests.
- There was a written protocol for advising patients of when to seek further medical advice for their health. This was in line with the recommended thresholds for body composition and bone density set out by the National Institute for Health and Care Excellence (NICE).
- Staff checked the identification of patients prior to scans by asking them to confirm their name, date of birth and address. There was explanatory information about The Society of Radiographers' 'pause and check' process and we observed the process being carried out. Patients also filled in a form indicating risk factors and women under the age of 55 confirmed that they were not pregnant before they were scanned.

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- If a client booked an appointment within 56 days of a previous appointment, Bodyscan would receive an automated email alert and the client would be emailed or called the same day to say that the appointment must be rescheduled. We were told that there had been a few occasions when someone had booked with too short an interval between their scans, and on every occasion the appointment had been moved so as to adhere to the protocol.
- One of the terms and conditions of bookings was: “I have not had a DEXA scan in the past eight weeks. Bodyscan will not permit scans more frequently than once every 56 days.” This was restated in the confirmation email and in the informed consents form, which every client signed immediately before the appointment. This was checked by the operator printing any previous scan report prior to a fresh scan.
- The service had a written cardiopulmonary resuscitation (CPR) policy which set out the policy for patients becoming unwell during consultations. The procedure was for staff to phone 999. Defibrillators were kept in the clinic where the service was situated which were to be used if the patient stopped breathing.

Staffing

- The service had enough staff with the right qualifications, skills, training and experience to keep clients safe from avoidable harm and to provide the right care and treatment.
- The service was staffed by one contracted operator, managed by the service manager who worked at the organisation’s other site but covered at this site where necessary. The service did not use bank or agency staffing. The service was occasionally covered by a further operator who worked for the service at another site. The service manager was the only direct employee of the service, all other staff worked on contract.
- Staff induction consisted of at least three months’ on-the-job training with the service manager as well as statutory and mandatory e-learning. Staff did not undertake appointments on their own until they had passed their introductory training period.

- The service had enough staff to run the service safely. The service was available to private patients through online booking only and patients were only able to book appointments when staff were available to fulfil them. Where the staff member had an unplanned absence the appointments would be covered by the manager of the service or delayed.
- The provider did not carry out risk assessments to minimize risks associated with lone working. The manager of the service acknowledged this risk when we raised it with them and was developing a lone working risk assessment following inspection.

Records

- The provider did not hold individual client records containing all the relevant client information in one place such as identity, medical conditions, consent, results of scans and any abnormality of results. Some individual information was kept but in different places/files. The provider told us that they did not store hospital records or communicate with the clients GP. They did not store any client records other than the DEXA body composition report, which served as the clinical evaluation of the scan and was handed to the client. We were concerned that a lack of comprehensive client records did not identify any risks associated with an individual client or guard sufficiently against the same person receiving repeat scans short of the recommended re-scanning period under a different name as well as difficulty the referral assessor verifying a repeat referral.
- The service kept copies of the DEXA reports in electronic portable document format, which was also provided to the client by email. The service kept an electronic copy for a month before it was deleted. However, the service was able to recreate the report from the cache (raw scan data) held on the DEXA scanner. The raw scan data was kept and archived once on the DEXA system and secondarily on an external hard drive (detached and in a locked cupboard) indefinitely in the DEXA system’s proprietary format. The service kept the raw scan data for seven years. We were given an example where a client who had received a scan three years ago had

Diagnostic imaging

requested a copy of their results. The service was able to input client criteria onto the DEXA scanner, such as: first and last name, date of birth and email address to retrieve a scan report.

- If a client was exposed to a greater dose of ionising radiation than intended, their name, date of and reason for overexposure and total dose was recorded in the incident reporting log. The RPA was also informed by email for any advice. This information was not kept in any individual comprehensive client record which would not be highlighted in the event of the same thing happening again.
- The service did not have contact with hospitals or patients' GPs. The service did not keep any medical records beyond the patient's DEXA body composition report, they did not share the reports with anyone except the patient.
- Patients were provided with a paper copy of their body composition report to take away with them and were also sent the report along with an explanatory document of their results electronically.

Medicines

- There were no medicines of any kind stored or administered as part of the service.

Incidents

- The service managed client safety incidents well. Staff recognised and reported incidents and near misses.
- Never events are serious, largely preventable patient safety incidents that should not occur if the available preventative measures have been implemented. The service had recorded no never events in the 12 months prior to inspection. The service had had no serious incidents or IR(ME)R reportable incidents in the 12 months prior to inspection. Staff understood the Duty of Candour and were able to describe thresholds where it would be appropriately applied, but had never had to do so.
- The manager demonstrated that when things went wrong, patients were apologised to and the service used the incident as an opportunity to learn and improve.

Are outpatients and diagnostic imaging services effective?

We do not give a rating for this question when we inspect diagnostic imaging services.

Evidence-based care and treatment

- The service provided care and treatment based on national guidance and evidence-based practice.
- Staff provided patients with a body composition report detailing fat content and bone mineral density and gave general advice on weight loss. Patients returning for follow-up scans could compare their results with their previous reports and against a data set made up of previous Bodyscan patients. The service did not give medical care, treatment or advice.
- Staff explained to patients that their body composition reports were indicative but not diagnostic. Where bone mineral density appeared outside of the normal range as prescribed by the National Institute for Health and Care Excellence (NICE) patients were advised to speak to their doctor and seek further testing. Though the service was up to date with NICE guidance, there was no formalised way of ensuring they remained up to date in the future. We raised this with the service manager who agreed that there was a need to regularly check NICE guidance in the future.

Nutrition and hydration

- Appointments with the service ranged from 20 to 80 minutes depending on whether they were a new or follow-up appointment and whether they were for one patient or a couple. Therefore, patients were not there for a significant length of time. As per the conditions of booking, "I understand that for the most accurate and reproducible result I should not eat or perform exercise for at least four hours before my scan", patients were requested to not eat but could drink water to be normally hydrated. Once the scan was completed there was water available from a cooler in the clinic waiting area.

Pain relief

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- This was not a service where pain management was required. However, staff were constantly with the patient during the consultation and scan and checked their comfort and anxiety levels throughout.

Patient outcomes

- Bodyscan is purely a measuring service. Information about the outcomes of patients' treatment was not routinely collected and monitored. Effectiveness as a service was measure primarily by patient feedback and the rate of patients who returned for follow up scans.

Competent staff

- The service made sure staff were competent for their roles.
- The service made sure staff were competent for their roles and there was ongoing support and supervision for all staff. Staff appraisals were carried out on an annual basis and all staff were up to date with their appraisals at the time of inspection.
- Staff only undertook consultations on their own when the manager was satisfied that they were adequately familiar with the mechanics of the DEXA scanner and understood body composition reports in order to evaluate and explain them to patients. IR(ME)R theory and practical training was given by the provider of the scanning equipment and was mandatory before staff undertook consultations.
- Staff undertook Bodyscan competency tests before they were allowed to give consultations and this competency was reviewed regularly through staff supervision.

Multidisciplinary working

- All those responsible for delivering care worked together as a team to benefit clients.
- There were not multiple staffing disciplines inputting to patient care.

Seven-day services

- The service was open four days per week. Opening times were dependent on the availability of the scanner which was rented from another service. There was no plan to extend these opening times.

Health promotion

- Staff gave clients practical support and advice to lead healthier lives.
- The service provided patients with general advice around nutrition and exercise to support them to achieve their body composition targets.

Consent and Mental Capacity Act

- Clients signed a consent form prior to their scan which confirmed their identity and included a clause explaining clients would be exposed to a very small dose of ionising radiation (X-Rays) equivalent to about one day's normal background radiation. Clients were informed of the risk of undergoing the scan in the consultation as well as on the service's website when they booked.
- There was a referral form and a consent form for every scan for every client. The operator signed and dated both forms to show: their authorisation of the scan against the justification criteria, and confirmation that the informed consent (including age and pregnancy status) were accepted by the client immediately before the scan. However, we saw no evidence or records to show that the referral assessor had approved the scan before it was given. There was no prior GP or other medical referral for the clients' scans. Notwithstanding any record, we were not assured that the referral assessor, in the absence of any prior medical referral, had the availability to review and approve each scan. For the protection of the client and for the protection of the scanning operator, the requirements for informed consent were not being met.
- Consent forms were stored temporarily in paper form in a locked cupboard in the room in which the DEXA scanner was housed. They were then digitally scanned in bulk by an external secure scanning service. The digital copies were sent to Bodyscan by secure file transfer protocol (FTP) server and then they were securely stored in a password-protected cloud storage for seven years. The original paper copies were securely destroyed by the scanning service after it was confirmed by Bodyscan that the digital versions had been received. Individual consent forms were not attached to any individual client record.

Diagnostic imaging

- The service did not carry out a body dysmorphia assessment on its clients.

Are outpatients and diagnostic imaging services caring?

Good 

We rated caring as **good**.

Compassionate care

- Staff treated clients with compassion and kindness, respected their privacy and dignity, and took account of their individual needs.
- During the inspection we observed one consultation which was a double appointment with two patients attending together. We observed that patients were treated with dignity and kindness and that staff communicated with patients clearly and openly. Body composition results were given in a compassionate, non-judgmental way.
- Patients' privacy and dignity was respected at all times. Patients were required to undress for their scan, this happened behind a closed door and with a curtain drawn.
- Data provided by the service showed that there had been 109 instances where patients had reviewed their experience with the service in the 12 months prior to inspection. Of these, 101 were five star out of five reviews and 8 were four stars. There were comments such as "first class experience from start to finish – I was delighted overall. [Staff were] so welcoming and reassuring" and "the experience was sensitively carried out and the results were explained fully".
- There were signs in the waiting area which informed patients that a chaperone was available should they wish to have one in their appointment.

Emotional support

- Staff provided emotional support to clients, families and carers to minimise their distress.

- Staff had a good understanding of the emotional impact of body composition reporting and were sensitive to the vulnerabilities and requirements patients visiting the service might have.
- The manager we spoke with gave examples of patients who had required further emotional support to manage their body composition. While staff understood that they were not qualified to give this support formally they were aware of the need for sensitive conversations with patients and they signposted patients to further support.

Understanding and involvement of patients and those close to them

- Staff supported and involved clients, families and carers to understand their condition and make decisions about their care and treatment.
- Staff answered patients' questions about the scanning process and the details of their body composition reports.
- Patients we spoke to felt they understood the scanning process from information given prior to their appointment and they gave positive feedback about how staff involved them in their treatment. Excellent patient feedback results showed that patients felt involved in the care and empowered by the service to make positive changes to their health and seek further support where necessary.
- Patients were entirely self-funded and there were appropriate and sensitive discussions about cost. Staff were clear with patients about the costs of treatment and discussed different treatment options.

Are outpatients and diagnostic imaging services responsive?

Good 

We rated responsive as **good**.

Service delivery to meet the needs of local people

- The service was open 9am to 5pm on Mondays and Wednesday, 12 noon to 8pm on Tuesdays and 10am to 8pm on Fridays. There were a variety of appointment times for patients to choose from.

Diagnostic imaging

- There was a main waiting area which was part of a separate clinic from which Bodyscan rented a room and the DEXA scanner. The waiting area was adequately sized, bright and airy. There was a water cooler and magazines and newspapers to read.
- Information was provided to patients prior to their appointment which included what to expect, how to find the service and what fasting as required.
- The facilities and premises were appropriate for the services delivered. The room in which the service was situated was large enough for two patients, the DEXA scanner, a computer and the Bodyscan operator with space for a changing area.
- Data provided by the service showed that there were 1357 scans in total, of which 690 included patient consultations, in the reporting period. Those scans which did not include consultations were follow-up scans to review progress.
- Data provided by the service showed that there were four unplanned cancellations of appointments in the reporting period. All cancellations were the result of a mechanical fault with the scanner. There were 20 delayed appointments which were also the result of mechanical faults.
- The service recommended that clients returned after 12 weeks if scan results suggested high body fat. If the data suggested an increased risk, then the service advised that further medical advice be sought from a GP or other healthcare professional. If the scanning operator felt that the clients would benefit from personal training advice, that option would be offered as the scanner had qualifications in personal training.

Meeting people's individual needs

- The service was inclusive and took account of clients' individual needs and preferences.
- New patient appointments were one hour for individuals and 80 minutes for couples. Appointments consisted of an initial discussion and identity check, scan, compilation of results and presentation and explanation of patients' body composition reports and questions. Appointment times were long enough to incorporate this.
- The service was wheelchair-accessible for patients with lift access to the clinic room. The scanner could support patients up to 200 kilograms in weight. The service's website asked patients who were over 180 kilograms to contact them prior to their appointment to discuss their requirements.

Access and flow

- People could access the service when they needed it and received the right care promptly.
- Patients could access the service when they wanted to. Patients were able to choose appointments through the service's website where all bookings were made. The service were always able to see patients within three days. There were no waiting times. Imaging results were given and discussed during the appointment.
- It was easy for people to give feedback and raise concerns about care received.
- The manager we spoke with told us that the service always tried to resolve complaints on the spot. There had been one formal complaint made in the reporting period which was a failure by staff to contact a patient who was late for their appointment due to not being able to find the location of the service. Staff subsequently gave the appointment slot to another patient. As a result when the first patient arrived late they could not be seen. This was resolved by the service manager with an apology and a free follow up scan.
- Themes from complaints and patient concerns raised informally were discussed between staff and used to ensure the service improved.
- The services' complaints documentation referred patients who were dissatisfied with the outcome of their complaint to the Local Government Ombudsman. The correct body for patients to refer to is the Independent Healthcare Sector Complaints Adjudication Service (ISCAS).

Diagnostic imaging

Are outpatients and diagnostic imaging services well-led?

Requires improvement 

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

Leadership

- Leaders had the integrity, skills and abilities to run the service. They understood and managed the priorities and issues the service faced. They were visible and approachable in the service for clients and staff.
- The service was run by a sole managing director who was also the registered manager. They split their time between two Bodyscan sites. The manager of the service had the right skills and knowledge and understood the challenges to quality and sustainability.
- Staff we spoke with described the manager of the service as “very personable and approachable” and told us there was regular communication between staff and managers. They told us they could speak to their manager if things went wrong. The manager was visible at the site and contactable to staff by phone and text at all times.

Vision and strategy

- The service had a vision for what it wanted to achieve in the future and a workable strategy for how to achieve it.
- There was a written business plan formulated by the manager and sole director of the service. This described the business model of the service and future plans for expansion.

Culture

- Staff felt respected, supported and valued. They were focused on the needs of patients receiving care. The service promoted equality and diversity in daily work, and provided opportunities for career development. The service had an open culture where patients, their families and staff could raise concerns without fear.
- Staff and the manager of the service we spoke with described a positive working culture where staff

worked collaboratively and with a common purpose to improve the service and care for patients. The manager of the service promoted a positive working culture by communicating regularly with staff and encouraging an open door policy.

- Staff told us they felt supported and valued and they spoke positively about working for the organisation. We heard examples of where action had been taken to address performance inconsistent with the organisation. There were mechanisms for ensuring staff development including appraisal. Staff were employed on flexible contracts which allowed them to develop their work externally to the service.

Governance

- The sole director of the company managed all day-to-day running of the service as well as all governance functions.
- The service had a comprehensive list of policies and procedures which staff could refer to to inform their work. Policies were available on the service intranet. Most policies were dated November 2018 and there were no review dates specified. This meant that there was no specified time at which the service would check their procedures remained relevant and in date.

Managing risks, issues and performance

- Risks to patients were identified in the service’s risk management policy. These included the risk of harm to patients from medical equipment or Bodyscan staff and the risks associated with ionising radiation. Each risk included mitigating factors and links to corporate policies including the safeguarding policy and IR(ME)R handbook.
- The primary risks to the service were mechanical failure and staff retention. There was a business continuity plan in place which provided the basis for returning the service to functionality in the event of an emergency. The plan specified two critical functions which were the ability to take bookings alone and to scan clients.
- However, the risks which we have highlighted in relation to record keeping, risk of non-pre-authorisation of scans and lack of informed consent were not mentioned on the risk register.

Diagnostic imaging

Managing information

- Patient information was managed through the service's intranet and backed up on a cloud-based server each day. Staff were able to access information when they needed it.

Engagement

- Following their appointment all patients received a link to a free text form in which to give their feedback to the service. The service used this information to improve, for instance by improving the online booking process in response to patient feedback.
- There was an annual staff meeting where all aspects of the service were discussed. There was regular contact

between staff and the manager through an electronic messaging group. Staff we spoke with felt that they were able to make suggestions about service improvement and that these would be considered.

Learning, continuous improvement and innovation

- All staff were committed to continually learning and improving services. They had a good understanding of quality improvement methods and the skills to use them. Leaders encouraged innovation and participation in research.
- The manager we spoke with described promoting a culture of learning and improvement through regular communication with staff and monitoring of the service. Each member of staff had a different background including nutrition, marketing and personal training.

Outstanding practice and areas for improvement

Areas for improvement

Action the provider **MUST** take to improve

- Ensure patient records are set up and maintained in line with the regulations contained in the Health and Social Care Act and its subsequent amendments
- Ensure that all criteria is met to satisfy informed consent
- Instigate adequate governance processes overall and in particular in relation to record keeping, consent, escalation and risk

Action the provider **SHOULD** take to improve

- Ensure that if a client has any questions at the stage of consent, that someone medically qualified is available to answer those questions

- Ensure that all staff receive training in informed consent
- Ensure all policies include future review dates
- Implement a formal process for remaining up to date with relevant NICE guidance
- Implement a formal process for escalating unexpected or concerning findings on scans
- The service should refer clients to the Independent Sector Complaints Adjudication Service (ISCAS) for further handling of complaints

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 12 HSCA (RA) Regulations 2014 Safe care and treatment</p> <p>Regulation 12 (2)(a)(b)</p> <p>(a) Assessing the risk to the health and safety of service users of receiving care and treatment.</p> <p>(b) Doing all that is reasonably practical to mitigate that risk.</p> <p>Clients self referred without prior medical referral. The registered person must ensure that for each client that self refers, there is a prior medical referral.</p> <p>We had doubts that the doctor (employed by a third party provider) had the opportunity to medically scrutinise and approve each referral before scans took place.</p>
Diagnostic and screening procedures	<p>Regulation 17 HSCA (RA) Regulations 2014 Good governance</p> <p>Regulation 17(1)(c)</p> <p>(c) Maintain securely an accurate, complete and contemporaneous record in respect of each service user.</p> <p>The provider did not hold individual client records containing all the relevant client information in one place such as identity, medical conditions, consent, results of scans and any abnormality of results.</p>