Bodyscan City

Quality Report

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

Ratings

Overall rating for this location	**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 (London City) is operated by Bodyscan Limited. The service uses a dual energy X-ray absorptiometry (DEXA) scanner to measure body composition and provide clients 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, also registered with CQC.

The service provides a diagnostic imaging service to adults only. We inspected this service using our comprehensive inspection methodology. We carried out the announced part of the inspection on 28 February 2019.

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

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

Services we rate

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

- 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.

However:

- Staff had a good understanding of safeguarding and gave examples of when a safeguarding referral would be triggered.
- The environment and equipment were suitable for the scans that Bodyscan undertook.
- Staff induction consisted of at least three months' on-the-job training with the registered manager, as well as statutory and mandatory e-learning. Staff underwent at least two months of one-to-one hands on training with real clients under direct supervision until they were competent. Clients were given a physical and electronic copy of their scans at the end of their appointments. The technology of the DEXA scanner allowed the service to retrieve the results of past scans.
- The service subscribed to The National Institute for Health and Care Excellence (NICE) alerts via Google News, and Bodyscan's director kept up to date with regulation changes.
- Staff had completed equality and diversity training and adhered to the provider's policy. Staff were always respectful and courteous, and as part of their induction process, this was monitored.
- Clients' privacy and dignity was respected at all times. Clients were required to undress for their scan; this happened behind a closed door and with a curtain drawn.
- During the service and consultation, staff kept the client informed every step of the way, checking their understanding and encouraging them to ask questions. All new clients had an hour-long appointment to ensure that there was enough time to discuss all that was needed. The scan itself took five minutes.

Summary of findings

- Staff had a good understanding of the emotional impact of body composition reporting. Staff were constantly with the client during the consultation and scan and checked their comfort and anxiety levels throughout.
- The service had effective systems to ensure that they were able to communicate with clients with hearing impairments. This included communicating with clients via text, email and having consideration for seating arrangements during consultations so that scanning operators could lip read if a patient had a hearing impairment.
- Bodyscan's DEXA body composition measurement service provided information that enabled individuals to measure and monitor their body.
- Appointment availability was good, and clients could book a same day appointment in some instances.
- The service only received one formal complaint and this was handled by the registered manager of the service.
- The number of compliments the service received between 1 November 2017 and 31 October 2018 was 153.
- The service director gave us a clear view of the future vision and strategy for the service which included expansion outside of London.
- The director was regarded as being a "a very good leader and boss" and was described as being visible and accessible to staff.
- The morale among staff was good and staff enjoyed working in the service, sharing in the knowledge of one another.
- The service had a risk register with clearly identified risks highlighted.

Name of signatory

Deputy Chief Inspector of Hospitals Nigel Acheson

Summary of findings

Our judgements about each of the main services

Service	Rating	Summary of each main service
Diagnostic imaging	Requires improvement 	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 City

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Summary of this inspection

Background to Bodyscan City

Bodyscan (London City) is operated by Bodyscan Limited. The service opened on 17 January 2017. It is a private screening facility situated in the City of London. The service accepts bookings online and patients are self-funded. It also accepts patient referrals from outside this area.

The service has had a registered manager in post since January 2017. The service is registered to provide diagnostic and screening services to patients over the age of 18. 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 City

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 scanning operator who facilitates the consultation and the service manager. We spoke with one client.

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 January 2019 there were a total of 2,374 client appointments. 759 of those visits were for first time client consultations and the remaining 1,615 were for follow-up scans. 100% of these were self-funded.

One Bodyscan scanning operator 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

- No never events
- No clinical incidents
- No serious injuries

No incidences of hospital acquired Methicillin-resistant Staphylococcus aureus (MRSA),

No incidences of hospital acquired Methicillin-sensitive staphylococcus aureus (MSSA)

No incidences of hospital acquired Clostridium difficile (c.diff)

No incidences of hospital acquired E-Coli

One complaint regarding a client who could not gain access to the floor where their appointment was via a pass-controlled lift.

Summary of this inspection

The five questions we ask about services and what we found

We always ask the following five questions of services.

Are services safe?

Requires improvement

We rated it 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:

- Staff had a good understanding of safeguarding and gave examples of when a safeguarding referral would be triggered.
- The environment and equipment were suitable for the scans that Bodyscan undertook.
- Staff induction consisted of at least three months' on-the-job training with the registered manager, as well as statutory and mandatory e-learning.
- Clients were given a physical and electronic copy of their scans at the end of their appointments. The technology of the DEXA scanner allowed the service to retrieve the results of past scans.

Are services effective?

It is not CQC policy to rate the effectiveness of this type of service. A **Not rated** rating was given:

- The service subscribed to The National Institute for Health and Care Excellence (NICE) alerts via the internet, and Bodyscan's director kept up to date with regulation changes.
- Clients were always offered water before their appointment, but most would attend with their own drinks.
- Staff underwent at least two months of one-to-one hands on training with clients under direct supervision until they were competent.
- Staff were constantly with the client during consultations and scans, checking their comfort levels throughout.

Are services caring?

Good

We rated it as **Good** because:

Summary of this inspection

- Staff had completed equality and diversity training and adhered to the provider's policy. Staff were always respectful and courteous, and as part of their induction process, this was monitored.
- Clients privacy and dignity was always respected. Clients were required to undress for their scan; this happened behind a closed door and with a curtain drawn.
- During the scan and consultation, staff kept the client informed every step of the way, checking their understanding and encouraging them to ask questions.
- Staff had a good understanding of the emotional impact of body composition reporting. Staff were constantly with the client during the consultation and scan and checked their anxiety levels throughout.

Are services responsive?

Good

We rated it as **Good** because:

- The service had effective systems to ensure that they were able to communicate with clients with hearing impairments. This included communicating with clients via text, email and having consideration for seating arrangements during consultations so that scanning operators could lip read for clients that had a hearing impairment.
- All new clients had an hour-long appointment to ensure that there was enough time to discuss all that was required. The scan itself took five minutes.
- Bodyscan's DEXA body composition measurement service provided information that enabled individuals to measure and monitor their body composition.
- Appointment availability was good and clients could book a same day appointment in some instances.
- The service only received one formal complaint during the reporting period 1 November 2017 and 31 October 2018 and this was handled by the registered manager of the service.
- The number of compliments the service received during the same period was 153.

Are services well-led?

Requires improvement

We rated it 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.

Summary of this inspection

However:

- The service director gave us a clear view of the future vision and strategy for the service which included expansion outside of London.
- The director was regarded as being a “a very good leader and boss” and was described as being visible and accessible to staff.
- The morale amongst staff was good and staff enjoyed working in the service, sharing knowledge with one another.
- The service had a risk register with clearly identified risks highlighted.

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

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.**
- Staff were 100% compliant in statutory training, which included Ionising Radiation (Medical Exposure) Regulations IR(ME)R Operator training, and IR(ME)R Theory training. This included fundamental physics of radiation and diagnostics; and radiation protection for radiation supervisors. A half day theoretical course on the education and training on ionising radiation, was completed in a classroom setting
- Staff working in the service received mandatory training in Safeguarding Adults Level 1 training. The director was Safeguarding Level 2 trained. The service did not see any persons under the age of 18 years of age. Other mandatory training received included: Data Protection, and Diversity and Equality training, of which staff were 100% compliant.
- All above training was undertaken online, however (BLS) Basic Life Support training, which also included a component of cardiopulmonary resuscitation (CPR) training, was received in a classroom setting.
- The director had received his BLS (basic life support) training with St John's Ambulance but had not received specific training to use the on-site resuscitation trolley. The contracted scanning operator at Bodyscan had not yet received his BLS Training. However, we were told he had been booked in to do his training on the 27 March 2019.
- A registration certificate was issued to Bodyscan by the Health and Safety Executive (HSE), based on information provided by the service director under 'Schedule 1'. In applying for registration with the HSE, the following items under 'Schedule 1' were confirmed:

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 had a good understanding of safeguarding. Staff were able to tell us the different types of abuse and the need to protect vulnerable adults and children (though the service did not see anyone under the age of 18). The service had never had to report a safeguarding concern but informed us that if they did, they would contact the police and the local authority social services department.
- We were given an example of where staff would sometimes see clients who may have presented with some psychological issues relating to food but this did not necessarily constitute a safeguarding concern. We were also given a number of potential examples that would constitute a safeguarding concern for example,

a client who had been forced to attend a scan, which would constitute a form of emotional abuse. A mental health component formed part of the safeguarding training.

Cleanliness, infection control and hygiene

- **The service controlled infection risk well.**
- The Bodyscan infection prevention and control policy contained detailed precautions that staff were required to take to minimise the risk of transmission of infection.
- There had been no incidence of a healthcare acquired infection in the previous 12 months.
- The consultation room contained a basket for used gowns, which were collected by a laundry contractor when staff emailed them to inform them that they were running low on clean gowns. We were informed that the contractor collected the dirty gowns at the same time as providing the service with clean ones.
- The consulting room floor was cleaned by cleaners daily. The cleaners were employed by the owners of the premises. The director told us that if he wasn't happy with the level of cleaning he would escalate the issues to the clinic director responsible for the premises.
- Bodyscan staff were responsible for cleaning the DEXA scanner, which was cleaned down at the start and end of each day and in-between clients, using disinfectant wipes and paper towels to dry.
- There was no sink in the clinic room. However, we were told that staff used the sinks shared with the other provider to wash their hands. The service did not carry out any hand hygiene audits.
- The only waste that Bodyscan collected was paper towels and disinfectant wipes, which was collected by the clinic cleaners of the provider who maintained the premises. Bodyscan undertook a deep clean of flooring when necessary, but we did not see a schedule of regular deep cleaning.

Environment and equipment

- **The design, maintenance and use of facilities, premises and equipment kept people safe.**
- The provider had a suitable environment and equipment for the service performed, and these were managed in a way which kept clients safe. Walls and doors had sufficient protection to reduce radiation penetration.
- Bodyscan rented a consulting room from another independent health provider, also registered with CQC, which contained a dual energy x-ray absorptiometry DEXA scanner. The fixed radiation dose provided by the DEXA scanner was 0.0042 mSv, which using data from Public Health England suggested that the dose was equivalent to one day's worth of background radiation.
- 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 a reason for this could be due to high humidity or extreme temperature in the room that would interfere with the machine. 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.
- The DEXA scanner at Bodyscan was calibrated to the equivalent scanner at Bodyscan's other site in Marylebone, which ensured that patients received accurate reports which they could compare if patients needed to go to the alternative location.
- We were shown evidence of results showing daily quality check (QC) tests that were performed on the DEXA scanner. The scanner would not operate until at least a daily spine phantom QC was run. The daily spine phantom quality check was used in measuring the accuracy and performance of the DEXA scanner, and ensured the best possible calibration and highest accuracy in patient results. The machine forced a body composition step phantom QC to be run every seven days, though this was also done every day, on the manufacturer's advice. The daily QCs were permanently logged in the DEXA system.
- The environmental dose rates were checked at commissioning. We were told by the registered

manager that there was no requirement for further checks, unless there was a major change (new hardware, relocation of equipment, etc.) Neither the supplier nor the radiation protection advisor were required to test environmental dose rates on a routine basis. There were no annual physics checks, as the daily phantom quality assurance (QA) provided enough reassurance that the machine was safe and working within specification.

- The manufacturer of the DEXA scanner provided twice-yearly preventive maintenance of the system to check operation and calibration.
- An environmental dosimetry survey was carried out over a period of two months and was reported on the 20 June 2017 by a physicist. A radiation dosimetry survey is the measurement, calculation and assessment of ionizing radiation dose absorbed by the human body. The results of the environmental survey were satisfactory and the physicist who signed off the report confirmed that the radiation shielding in and around the DEXA unit was adequate and the current radiation designations of the DEXA room and surrounding areas were appropriate. No remedial action was required.
- The registered manager of the service was the designated radiation protection supervisor. Bodyscan had a set of local rules. Local rules summarised the key working instructions intended to restrict exposure in radiation areas. They included the following information: a description of the area covered by the rules and its radiological designation. The local rules for Bodyscan were displayed appropriately, up-to-date, and staff were aware of them.Bodyscan had a written agreement from the host provider to use their toilet facilities and reception area, they also had access to a first aid box and a resuscitation trolley.

Assessing and responding to patient risk

- **Staff completed and updated risk assessments for each client and removed or minimised risks.**
- 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.
- 'The referral assessor worked for Bodyscan, under the 'Employers Procedures IR(ME)R 2017' regulation. The referral assessor is a clinician and had relevant training specific to the scope of practice, which included completing an IPEM e-IR(ME)R Integrity Course.' Given that the referral assessor was employed elsewhere and that there was no prior GP medical referral for clients to this service we were not assured of their availability to check all referrals before scans were performed or to deal promptly with any complex issues that might arise.
- The service did not use bank or agency staffing
- The type of DEXA scanner used by the service issued only a very low and fixed dose of ionizing radiation. The fixed dose of radiation equivalent to less than a day's exposure to natural radiation. The staff member facilitating the scan stayed in the room with the client, generally standing behind a screen. Access to the room where scans were carried out was restricted. The door to the room was locked during scans and there was a 'Radiation controlled area' and 'authorised persons only' sign on the door indicating that there was radiation present. In the event of an emergency, a member of staff could access the room from outside.
- There was a radiation protection advisor (RPA) available who was based at an NHS hospital. A suitable radiation protection advisor is an individual that meets the health and safety executive criteria of competence and has the necessary experience and expertise to advise on the organisation's uses of ionising radiation.
- Managers and staff we spoke with were aware of the need to escalate unexpected or concerning findings on the scans. However, there was no formal process for doing this.

Diagnostic imaging

- There were no clients who were transferred from the location to another health care provider in the last 12 months in an emergency. Bodyscan staff had access to a first aid kit and resuscitation trolley if such an event were to occur.
- There was a written protocol for advising clients 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 clients 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. Staff also checked the pregnancy status of women. Bodyscan City's protocols stated the criteria for informing the clients when they should seek general or specialist medical advice (e.g., an indication of low bone density, high visceral fat). Bodyscan City did not provide expert medical advice itself. Also, in Bodyscan's referral protocols clients could not return in less than eight weeks. The service director told us that clients would be advised on an optimum time for them to return depending on the treatment regime.
- 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 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.
- Bodyscan staff had access to a first aid kit and resuscitation trolley in such an event that the need for it arose.

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 scanning operator managed by the service director/registered manager who occasionally worked at the location, who also covered at the Marylebone location when necessary.
- The service director, who was also the registered manager for the service was not a registered healthcare professional by occupation. However, they became a radiation protection supervisor (RPS) after completing a two-day course run by their (radiation protection advisor) RPA, which we saw evidence of.
- The service had enough staff to run the service safely. Clients were only able to book appointments when staff were available. If a staff member had an unplanned absence, the appointments would be covered by the clinic director, or rescheduled to another day. In the unlikely event where both self-employed scanning operators (the other working at the Marylebone location) were absent at the same time, the director would be unable to carry out all contracted appointments. We were told by the director that he would try to ensure that there were no more than three consultations performed consecutively in a day, as they were long appointments and could be quite taxing on staff, especially as they had no one to relieve them for a break.
- There were no current vacancies in the service at the time of our inspection.
- The service did not carry out risk assessments to minimise 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

Diagnostic imaging

- 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 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.
- We observed that there was a shredder in the consulting room. The printed copy of the DEXA scan was given to the client to take away. Printed copies of previous scans were produced for appointments where clients were attending for a follow-up appointment. However, we were informed that if these clients did not attend, then that report was shredded immediately.
- Consent was obtained by the scanning operator consulting with the clients and going through the consent form with them, ensuring they understood and met the criteria for receiving a scan. 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.

Medicines

- Controlled drugs were not stored or administered as part of the services that Bodyscan provided.
- As the service did not store or administer any medicines, there was no need to use non-medical prescribers or patient group directions (PGDs) in the service.

Incidents

- **The service managed client safety incidents well. Staff recognised and reported incidents and near misses**.
- Never events are serious client safety incidents that should not happen if healthcare providers follow national guidance on how to prevent them. Each never event type has the potential to cause serious client harm or death but neither need have happened for an incident to be a never event.
- From 01 November 2017 to 31 October 2018, the service reported no incidents classified as never events.
- The service reported no serious incidents or IR(ME)R/ IRR incidents in the reporting period 1 November 2017 to 31 October 2018.

- The director explained to us how an incident could be reported in an incident reporting log book that was held in the consulting room. The scanning operator had so far not needed to report an incident in their employment.
- Though the DEXA scanner would only give out a fixed dose of radiation, any technical or mechanical issue arising with the scanner, which meant that a client would have to be scanned again, would trigger the need for an incident report to be completed. We were told by the scanning operator that if such issue arose, he would notify the: director, the RPA, as well as the client, with the incident being reported into an incident reporting log book that we were shown on the inspection.
- Radiation doses of 0.0042 mSv were fixed. However, when a client was exposed to further radiation due to being re-scanned, because of machine failure, the incident was recorded in the incident report (for an exposure greater than intended) and fault report (for the mechanical fault). The RPA was informed by email so that they were aware and could provide advice as necessary.
- We saw a letter dated 11 December 2018 that was sent by the director to the RPA for a client who was "subject to two full body scans as the first presented an error…". The letter also described instructing the client to leave the room whilst a body composition quality check and radiographic uniformity test was performed on the scanner, which passed, which then meant that the client could be rescanned. The letter was sent to the RPA because of a machine malfunction, which consequently meant that the client had to be rescanned again and exposed them to a double dose of radiation. We saw a response from the RPA, which required the service to take no further action as the client's exposure to the dose of radiation was so low.
- The director and scanning operator demonstrated a good understanding of Duty of Candour (DoC). We were given an example of how the service would respond if for example, a client had received inaccurate results because of a DEXA machine malfunction or error, then the client would receive an apology and explanation of how it occurred. Following on from this, if the client then agreed to a further opportunity to be rescanned, it would then be explained to them that they would not be over exposed to radiation, as the dosage was quite small.

Are outpatients and diagnostic imaging services effective?

We do not rate the effective domain for this type of service**.**

Evidence-based care and treatment

- **The service provided care and treatment based on national guidance and evidence-based practice.**
- The report provided to clients was not a diagnostic report. It gave an overall reading for bone density but was not an accurate measure. Body mass index was also identified. There was a clause in the consent form that stated that clients would agree to follow the advice of the scanning operator, or in the explanatory notes that would accompany their Bodyscan report. If for example, a client attended for a scan, this could trigger the need for the client to be followed-up with a consultation with a GP or other appropriately qualified medical professional.
- The service subscribed to The National Institute for Health and Care Excellence (NICE) alerts via the internet and Bodyscan's director kept up to date with regulation changes. For example, some updates were received through their RPA. We were given an example of a change in regulation where the director had to register the business with Health and Safety Executive (HSE). The director also registered with the Information Commissioner's Office for data protection.

  Results from an annual Radiation Protection Advisor/ Medical Physics Expert (RPA/MPE) audit carried out on 25 May 2018 and reported on in July 2018, showed that the auditee (the registered manager) was fully compliant in measures such as: optimisation of client dose, IR(ME)R Schedule 2 procedures, health and safety structure, referral criteria, referrers – procedure for identifying referrers within specified scope of practice, operators – operators had received equipment specific training, and practitioners

followed practitioner authorisation guidelines. One of the recommendations from the audit were that the radiation protection policy should be updated to ensure that it referred to the Ionising Radiations Regulations 2017 (rather than IRR 1999) and the Ionising Radiation (Medical Exposure) Regulations 2017 (rather than IR(ME)R 2000). The audit was carried out by a Radiation Protection Advisor (RPA) and Medical Physics Expert (MPE), who worked at a London NHS trust.

Nutrition and hydration

- Clients were always offered water before their appointment, but most attended with their own drinks.

Pain relief

- There were no arrangements for supplying pain relief and it was highly unlikely that a client would experience any pain or level of discomfort. The potential for discomfort was small as the scan involved clients laying on their back, on a padded mattress for four minutes. There was also a video on the home page of the website showing precisely how a scan progressed.
- We were told by the service director that the service did not have any clients who stated that they were ever in pain.

Patient outcomes

- The Bodyscan service primarily measured body fat and advised, informed and motivated its clients to improve and said they were not in the business to take clients to 'low fat'. The DEXA body composition scan did not provide any diagnosable images or data that would identify a fracture or other condition, and as such the service did not refer clients to medical specialists.
- If a client was attending for a follow-up scan, then the service was able to track each of the client's results from their previous visits. The DEXA report allowed for six of the client's progressions to be shown adjacent to one another.
- The director told us that they were constantly trying to improve the quality of the service, and were currently trying to improve the body composition calculator. Though the manufacturer of the DEXA scanner didn't actively seek feedback about the machine, we were told by the director that he provided feedback to the Chief Scientist of the manufacturer, feeding back his findings, having used the DEXA scanner for over 1,000 scans.

Competent staff

- **The service made sure staff were competent for their roles.**
- 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 consultations on their own until they had passed their introductory training.
- Staff underwent at least two months of one-to-one, hands-on training with clients under direct supervision until they were competent. Once they had gained enough experience, successfully completed their mandatory training and demonstrated competence, the registered manager visited them on the job to ensure that they were executing their tasks competently.
- Staff also underwent a competency test to ensure they were competent in all aspects of the operation of the DEXA scanner. We were told that operating the machine and engaging with the client were the two areas of focus for anyone working in the service. The director told us that he sat in on consultations so that he could get an indication for how the operator was working and also share his knowledge where appropriate too.
- We saw evidence that the service director attended a core of competence course on 'Radiation Protection for Radiation Protection Supervisors and Quality Assurance in Radiology'.
- Bodyscan's operators, referrer and practitioner were all documented and existed under a process of entitlement; entitlement came from the service director. We saw evidence of their qualifications and experience. For example, Bodyscan's operators had to obtain an IR(ME)R theory certificate and complete DEXA operator training and a more advanced DEXA competency test.

Diagnostic imaging

- Appraisals were completed annually for each of the scanning operators working across the two locations.

Multidisciplinary working

- **All those responsible for delivering care worked together as a team to benefit clients.**
- The manager and two scanning operators who ran Bodyscan services had backgrounds in DEXA scanning, nutrition, corporate marketing and personal training. Staff we spoke with described learning from each other, as to how they could better interact with and advise clients to improve the service.
- Clients attending the service only saw one member of staff for their consultation and scan. Staff shared best practice and discussed when things had gone wrong to ensure clients received a consistent service, irrespective of which member of staff they saw.

Seven-day services

- The service operated Monday to Friday and the occasional Saturday. Hours of operation varied, and opening times could start at 8:40am or 11am and close at 4pm or 7pm. The business operated its opening hours alongside those of the provider that they rented a consulting room from.

Health promotion

- **Staff gave clients practical support and advice to lead healthier lives.**
- Bodyscan provided clients with general advice around nutrition and exercise to support them to achieve their body composition targets. The service also provided clients with information about obesity and nutrition, through the service's blog page on the Bodyscan website. The service would also answer any questions a client may have had directly after the scan or in a follow-up email.

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 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.
- 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

Requires improvement

Diagnostic imaging

- **Staff treated clients with compassion and kindness, respected their privacy and dignity, and took account of their individual needs.**
- The service provided an environment that was welcoming, warm, friendly and non-judgmental.
- Staff had completed equality and diversity training and there was an equality and diversity policy, which staff adhered to. The director monitored how new staff interacted with clients as part of the induction process.
- Clients displaying some level of anxiety, or those struggling with their weight were treated with compassion. There was an emphasis on putting them at ease and explaining processes. The service was sensitive to each person's needs and motivations for using the service including obesity, self-image problems, a poor relationship with food.
- Clients' privacy and dignity was always respected. Clients were required to undress for their scan; this happened behind a closed door with a curtain drawn.
- We were told by the director of Bodyscan that as a private service, he knew that clients would not return unless they were treated with respect, warmth and dignity.
- During the service and consultation, staff kept the client informed every step of the way, checking their understanding and encouraging them to ask questions. By facilitating a discussion rather than a lecture, staff ensured that the service was caring and collaborative.

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 clients visiting the service might have.
- The manager gave examples of clients who had required further emotional support to manage their body composition. Staff were aware of the need for sensitive conversations with clients and they signposted clients to further support.
- Staff were constantly with the client during the consultation and scan and checked their comfort and anxiety levels throughout.

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 clients' questions about the scanning process and the details of their body composition reports.
- Clients we spoke with 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. Client feedback results showed that clients felt involved in their care and empowered by the service to make positive changes to their health and seek further support where necessary. Some of the feedback given about the service, included: "Very interesting and informative session. Great explanation and supporting documentation". "Body scan has really given me the information that I needed in order to make some significant changes to way I train as well as eat".
- Clients were self-funded and there were appropriate and sensitive discussions about cost. Staff were clear with clients 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

- Bodyscan provided a service not provided by the NHS, which allowed clients to better manage their own health.

Meeting people's individual needs

- **The service was inclusive and took account of clients' individual needs and preferences.**

Diagnostic imaging

- All appointments were booked online so there was very little telephone communication.
- We were told that the Marylebone site was more accessible and was completely step free. If wheelchair users booked appointments, we were told that these clients were encouraged to attend that location as it was better suited to their accessibility needs.
- All new clients had an hour-long appointment to ensure that there was enough time to discuss all that was needed. The scan itself took four minutes.
- The director outsourced its telecommunication solutions to an independent company, who would answer clients calls. They were equipped to deal with logistical enquires, and there was a FAQs (frequently asked questions) page on Bodyscan's website that the telephone company could signpost clients to. However, we were told that for more technical queries that they were not able to answer, the contact details of the clients were taken so that the director could call them back.
- There was a non-discrimination policy that the service used to ensure all clients were treated fairly and were not being discriminated against the protected characteristics. We were given examples of clients that Bodyscan had seen in the past such as transgender clients and amputees. Clients who were over 200 kilograms in weight would not have access to scans, not because they were being discriminated against but because the manufacturer of the DEXA scanners did not manufacture tables beyond that weight.
- The scanning operator described how they would tap into clients' motivations, who typically were sedentary and trying to lose weight. Understanding the client's objectives, allowed them to explain the outcome of scans at a level that they would understand in relation to their own knowledge-base, which we were told had also improved their practice as a scanning operator.
- If someone were unable to lie still for four minutes then the service would have to cancel the appointment, refund their payment and advise an alternative method of establishing their body composition (such as bio-impedance analysis). This had not happened to date.
- The service reported that they had a handful of clients who had asked for something to support their heads, so the service provided a rolled-up towel for this purpose.

Access and flow

- **People could access the service when they needed it and received the right care promptly.**
- From the 28 February 2018 to 27 February 2019, the service scanned 1,615 clients, with 759 of those clients attending as a first-time client receiving a consultation. We were told that clients could easily rebook within days if they missed their first appointment provided the set referral criteria were still met.
- The registered manager responded to all written (emailed) enquiries by email or phone. Clients chose a date and time and their preferred location using an online booking system. We were told that there was always sufficient capacity to see new clients within one to three days.
- Machine breakdown or staff absence were the most likely reasons for the service having to cancel an appointment. If it did happen, then clients would be offered an appointment at the other location. Clients would be given a refund if the service cancelled within 24 hours. If a client was five minutes late for a 20-minute follow-up appointment and 10 minutes late for an hour consultation, there was a chance that they may not be scanned.
- The service used a text messaging system to remind clients of an appointment two hours before an appointment and an email reminder was sent out 36 hours before. This ensured that clients remembered their forthcoming appointment, and had the time to provide notice of cancellation if they could not attend.
- The service did not operate a waiting list. Waiting times on the day of a client's scan were low because the service usually ran to time. DNAs (did not attends) were always marked as a no show in the calendar.
- Follow-up scans enabled clients to accurately monitor their progress (especially in fat loss) over time. We were told that Bodyscan City had clients who had been returning regularly since the company started in 2015.

Requires improvement

Diagnostic imaging

- 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 nutritional advice, that option would be offered as the scanner had qualifications in nutrition.
- From 1 November 2017 to 31 October 2018, the total number of planned procedures/examinations that the service cancelled was one. This reason for this cancellation fell under the category of 'machine breakdown or other equipment failure' but more specifically, the software used as part of the DEXA scanner had failed to write to disk.
- From 1 November 2017 to 31 October 2018, the total number of planned examinations/procedures the service delayed was three. The most frequent reason for the delay was preventative maintenance or other non-critical maintenance. This would have occurred if the clients' appointments were booked and in the diary before the preventive maintenance was scheduled. This figure represents just 0.2% of all bookings, meaning 99.8% of bookings were not delayed or postponed.

Learning from complaints and concerns

- **It was easy for people to give feedback and raise concerns about care received.**
- We were provided with an example of the complaints form that clients could complete if they were dissatisfied with the service they received, or needed to make a complaint for some other reason. The form included the named individual that clients could send their complaints to. Clients could also hand the forms to a member of staff, or send their complaint via email or by post. Complainants were encouraged to contact the local government ombudsman if they were dissatisfied by the handling or response of the complaint by Bodyscan. However, the independent body that handle complaints that the service should have been referring its clients to was the Independent Sector Complaints Adjudication Service (ISCAS).
- Anyone could make a complaint using the methods above.
- Scanning operators were directed to feed verbal client comments to the registered manager so that improvements could be made, and shortfalls addressed.
- There was a complaints policy on the website.
- From 1 November 2017 to 31 October 2018, the number of complaints the service received was one. We were given an example of one unofficial complaint relating to a client who could not gain access via the pass-controlled lift. This resulted in the client being late for his appointment and not being seen. Because of this, the service changed their system so if a client was late, the scanning operator would call the client to establish where they were and send them a message instructing them that they could gain access via the side door of the building, as this was always accessible. The client in question was emailed after the event, apologised to and was refunded the amount of the scan cost. They were also given additional free sessions and an explanation was provided to them as to why they would have encountered difficulties in accessing the floor to get to their scan.

Compliments

- The number of compliments the service received from 1 November 2017 to 31 October 2018 were 153.

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 director opened the Bodyscan City location in 2016 and the Marylebone location in 2015, having seen a similar business model work in Australia.

Diagnostic imaging

- In information provided to us by Bodyscan, we were told that the director for the organisation had "built the business single-handedly from a blank sheet of paper to a small but successful and growing business". We were told that the director's background in corporate marketing and client service, kept new clients coming through the doors, and his focus on "customer delight" and staff training encouraged repeat custom.
- The director often sat in on the scanning operator's clinics. The director was described as "a very good leader and boss". We were told by the scanning operator that the director was "very helpful" and would travel into the service very quickly if he was needed. There were always open lines of communication between the director and operator, communicating daily by telephone.
- In addition to the occasions where the director covered in the event of sickness or annual leave, he also worked at the City location two days a week.

Vision and strategy

- The service director gave us a clear view of the future vision and strategy for the service which included expansion outside of London. However, we were told that the scarcity of a third (second-hand) DEXA scanner, was delaying the implementation of the third premises. Conversely, the cost of purchasing a new scanner or leasing one presented risks in terms of Bodyscan's cashflow.
- Improving the quality of consultations via staff training and introducing data visualisation tools, was an area the service was keen to achieve. Data visualisation was seen as an initiative that could increase the impact of clients' results during their consultation and help them understand the data in their report and where they 'sat' in the population more easily.
- We were told that Bodyscan City's director was liaising with an independent business growth analyst to look at ways of further growing the business.

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.**
- Though the Bodyscan services were staffed by only three members of staff, the culture of the organisation was described by one of the scanning operators as a "very good place to work". We were told that there was always transparency between scanning operators and the director. We were told by a member of staff that they enjoyed working in the service and had relocated to work in the service, and felt supported by the director in their relocation.
- A group chat room had been formed via a social media platform, and each member of staff subscribed to it. This enabled constant communication between the three staff in and outside of work.
- We observed that morale amongst staff was very good. The scanning operator at the City location had skills in nutrition, the operator at the other Bodyscan location had skills in personal training and the director had experience in using the DEXA scanner, which meant that the team complimented each other very well.

Governance

- The director, who was also the registered manager was responsible for governance arrangements and quality monitoring. They had systems for monitoring training of his staff, as well as systems for monitoring and being updated about risk assessments carried out on the premises by the host provider.
- The scanning operator understood their responsibilities as the operator of the DEXA scanner machinery and that the machine gave a fixed dose of radiation. They were also aware of the need to escalate to the director any mechanical or technical faults with the scanner.
- There was no specified time at which the service would check that their procedures remained relevant and in date. The service had a comprehensive list of policies and procedures which staff could refer to inform their work. Policies were available on the service intranet. Most policies were dated November 2018 and there were no review dates specified.

Diagnostic imaging

- We found deficiencies in record keeping and lack of good governance in relation to the lack of comprehensive individual client records, authorisation of scans pre-scan and the lack of processes to ensure informed consent.

Managing risks, issues and performance

- We were provided with a risk register, which outlined three risks and the controls. Risk ratings of "low" or "very low" were attached to these three risks.
- 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.
- For example, on the risk register the provider identified excess or unnecessary exposure was highlighted as a risk in November 2018. Those at risk were categorised as operators, clients carers, visitors, clinical staff, cleaners and maintenance staff. Controls for this identified risk were measures such as: designation of the DEXA room as a controlled area; local rules for the DEXA room; no casual access permitted, with the door being locked during radiation exposure and outside operating hours; an environmental dose meter audit; an appointed radiation protection advisor and a named radiation protection supervisor; a regular service contract with maintenance by trained engineers; and daily and weekly quality assurance checks that were automatically collected by the DEXA machine. The standards that the service followed in relation to this risk were: RPC (Radiological Protection Centre), IR(ME)R, Ionising Radiations Regulations IRR17 and local rules.
- The service identified other risks that had no impact on client safety and client care. One was a reduction in first-time clients and how this could affect the financial strength of the business.
- The service had a written business continuity plan. The director told us that in the event that the City location was affected by a power outage, or other circumstance that would render the service unable to serve its clients, then he would get in contact with his outsourced telephone company to ring each of his clients and offer them an appointment at his other Bodyscan location in Marylebone.
- We were told by the scanning operator that the challenges that they faced in their role were the diversity of clients they met, with each of them having their own unique goals that they were hoping to achieve.

Managing information

- Information technology systems were described as efficient and working well. Bodyscan had its own contract with an internet provider, so were not reliant on the Wi-Fi of the provider that they were renting a room from. There were no data protection breaches in the service. Bodyscan had a Privacy and Confidentiality Policy and all employees underwent Data Protection Training as per the job description.

Engagement

- All clients received a link to a free-text form in which to give their feedback about the service following their appointment. The service used this information to improve, for instance by improving the online booking process in response to client 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 a social 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 director stressed the importance of technology to improve the business, though in some regards it was stuck by the constraints of the DEXA technology.
- There was a plan to improve the functionality of the online body composition calculator.

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	Regulation 12 HSCA (RA) Regulations 2014 Safe care and treatment Regulation 12 (2)(a)(b) (a) Assessing the risk to the health and safety of service users of receiving care and treatment. (b) Doing all that is reasonably practical to mitigate that risk. 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. 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.

Regulated activity	Regulation
Diagnostic and screening procedures	Regulation 17 HSCA (RA) Regulations 2014 Good governance Regulation 17 (1)(c) (c) maintain securely an accurate, complete and contemporaneous record in respect of each service user. 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.