

Opus Diagnostics

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

Good 

Are services safe?

Good 

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

Letter from the Chief Inspector of Hospitals

Opus Diagnostics is operated by Berkshire Medical and Imaging Centre Ltd. The service is located on a small business park in Ascot, close to the train station and was purpose built. It provides diagnostic imaging to support the treatment of musculoskeletal disorders.

The service is on two floors. The reception and main waiting room are on the ground floor, with secured access to the magnetic resonance imaging (MRI) and X-ray rooms, changing rooms and toilet. The MRI unit uses magnetic fields and radio waves to produce detailed images of the insides of the body and the X-ray equipment uses radiation to create images.

On the first floor there are separate rooms for the dual-energy X-ray absorptiometry (DEXA) unit and the ultrasound scanner. The DEXA unit uses X-rays, most commonly to assess bone density, and the ultrasound equipment produces scans from high-frequency sound waves. In addition, on the first floor there is a nursing station and small waiting area, the office, a radiology reporting room, a staff kitchen and a further toilet. As well as stairs, there is a lift to the first floor and the facilities have been designed to accommodate people in wheelchairs.

The service is registered to provide two regulated activities; diagnostic and screening procedures and treatment of disease, disorder or injury. It provides diagnostic imaging for adults, children and young people.

We inspected this service using our comprehensive inspection methodology. We carried out the short-notice (48 hours) announced inspection on 13 December 2018 and telephoned patients to ask them about their experiences of care on 18 and 19 December 2018.

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

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

We rated this service as **Good** overall.

We found the following good practices at this diagnostic and imaging service:

- 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.
- Staff kept the premises clean, for the most part.
- Staff reviewed and updated risk assessments for each patient, using the referral forms and tailored patient questionnaires.
- The service had enough staff with the right qualifications, skills, training and experience to keep people safe.
- Staff kept detailed records of patients' care and treatment.
- The service followed best practice when prescribing, giving, recording and storing medicines.
- The service had systems to manage patient safety incidents.
- The service had contracted support from an accredited Radiation Protection Advisor and a Medical Physics Expert.
- The service provided care and treatment based on national guidance and evidence of its effectiveness.

Summary of findings

- The service offered people appointment times to reflect their needs and preferences, for example if they required fasting or were diabetic.
- Managers monitored the effectiveness of care and used the findings to improve them. They carried out multi-disciplinary meetings to evaluate images and techniques to improve image quality for the benefit of patients.
- The service made sure staff were competent for their roles. There were systems to check staff professional registrations, appraise their work and provide support.
- Staff understood how and when to assess whether a patient had the capacity to make decisions about their care.
- The service planned and provided services in a way that met the needs of local people. The environment was appropriate and comfortable for patients, including those with mobility needs.
- The service arranged appointment times to suit patients.
- The service supported carers to be with patients for reassurance during their X-ray, using a recognised consent procedure to explain the risks of ionising radiation exposure to the carer.
- The service had not received any concerns or complaints since opening in July 2018 but staff recognised the importance of taking complaints seriously and learning from them.
- The service had a vision for what it wanted to achieve and workable plans to turn it into action. Service managers were involved in developing these plans.
- Managers promoted a positive culture that supported and valued staff, creating a sense of common purpose based on shared values. Staff reported their team worked well together and staff trusted and respected each other.
- There was a strong emphasis on patient-centred care. Staff promoted openness and honesty and understood how to apply the duty of candour.
- The service collected, analysed, managed and used information well to support all its activities, using secure electronic systems with security safeguards.
- The service had engaged with local organisations to plan services, and had plans to seek patient feedback once more established.
- The service was committed to improving services by learning from when things went well or wrong, promoting training and innovation. The service held regular learning meetings involving the radiographers, radiologists and orthopaedic surgeons to improve the quality of their images.

We found areas of practice that required improvement:

- There were gaps in the systems for monitoring equipment cleaning.
- A staff member had started work, although in a shadowing capacity, without having completed all the safe recruitment checks.
- The governance arrangements were not clear and had not been evaluated. There was not a systematic approach for reviewing all aspects of quality and safety.
- The provider had not developed a means of identifying and managing risks to the service going forward.
- The provider's policies did not always reflect the specific activities carried out by the service. For example, the accident and incident reporting policy and procedure did not refer to accidental or unintended exposure to radiation or how to report such incidents.

Nigel Acheson

Summary of findings

Deputy Chief Inspector of Hospitals (London and South)

Summary of findings

Our judgements about each of the main services

Service

Diagnostic imaging

Rating

Good



Summary of each main service

This was a limited company providing a diagnostic imaging service.

We rated this service as good because it was safe, caring and responsive. The governance and risk management arrangements required improvement. We do not rate effective for this type of service.

Summary of findings

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Good



Opus Diagnostics Ltd

Services we looked at

Diagnostic imaging

Summary of this inspection

Background to Opus Diagnostics

Opus Diagnostics is operated by Berkshire Medical and Imaging Centre Ltd. The service opened on 2 July 2018 and provides diagnostic imaging services in Ascot, Berkshire. The service primarily serves the communities of the surrounding area, however medicolegal services referred patients from a much wider area. Opus diagnostics did not have a contract to provide services for

NHS patients when we inspected. The service is registered to provide two regulated activities: diagnostic and screening, and treatment of disease, disorder or injury.

The hospital has had a registered manager in post since first opening.

This inspection took place on 13 December 2018 and we telephoned patients to ask them about their experiences of care on 18 and 19 December 2018.

Our inspection team

The team that inspected the service comprised a CQC lead inspector and a specialist advisor with expertise in diagnostic imaging. The inspection team was overseen by Amanda Williams, Interim Head of Hospital Inspection for South Central and South London.

Information about Opus Diagnostics

During the inspection, we reviewed the premises, equipment and documentation. We spoke with five staff; the registered manager, radiographer, radiographic department assistant, receptionist and a radiologist. We spoke with six patients. During our inspection, we reviewed five sets of patient records.

There were no special reviews or investigations of the service ongoing by the CQC at any time during the 12 months before this inspection. This was the first inspection of the service since registration with CQC, five months previously.

Activity and track record since opening in July 2018 and reporting in October 2018:

- The service had not taken images for any NHS funded patients.
- Three radiologists worked at the hospital under a self-employed contract. Opus Diagnostics employed a full-time manager/radiographer and three further

radiographers. In addition, it employed six part-time or zero hours contract registered nurses, two healthcare assistants, two receptionists and a radiographic department assistant.

- There were no staff vacancies and the service did not use agency staff.

Track record on safety:

- Zero Never Events
- Zero clinical incidents
- Zero incidents of hospital acquired infections
- Zero complaints.

Services accredited by a national body:

- The service had no accreditations.

Services provided under service level agreement:

- Clinical and non-clinical waste removal
- Laser protection and medical physics services

Summary of this inspection

- Laundry
- Maintenance of medical equipment
- Building maintenance
- Human resources and health and safety advice
- Business policy support

Summary of this inspection

The five questions we ask about services and what we found

We always ask the following five questions of services.

Are services safe?

We rated it as **Good** because:

Good



- The service provided mandatory training in key skills to all staff and made sure everyone completed it. Staff completed an induction and said they were supported to attend their training.
- Staff understood how to protect patients from abuse. The registered manager and senior radiographer had both completed adult and child safeguarding training to level 3, and the registered manager was the safeguarding lead. There was information about safeguarding on display in the waiting room for both patients and staff to refer to.
- Staff generally kept the premises clean. They used control measures to prevent the spread of infection.
- The service had suitable premises and equipment and looked after them well. The premises had been designed to deliver diagnostic imaging services and to meet the needs of patients. There were systems to ensure the equipment was safe for patients and staff.
- Staff reviewed and updated risk assessments for each patient, using the referral forms and tailored patient questionnaires. Staff checked patient identity and the area to be scanned, for example to minimise the risks of radiation exposure. They also checked patients were suitable for the type of scan requested.
- The service had enough staff with the right qualifications, skills, training and experience to keep people safe from avoidable harm and to provide the right care and treatment. The service ensured there were always at least two staff members on site during working hours.
- Staff kept detailed records of patients' care and treatment. The electronic records were up-to-date, of high quality and easily available to all staff providing care.
- The service followed best practice when prescribing, giving, recording and storing medicines.
- The service had systems to manage patient safety incidents. There had been no incidents relating to patient safety since the service had opened but staff understood how to recognise and report an incident.

However, we also found the following issues that the service provider needs to improve:

Summary of this inspection

- There were gaps in the systems for monitoring equipment cleaning. We saw dust on the top of the MRI equipment and cleaning checklists were not maintained.
- A staff member had started work, although in a shadowing capacity, without having completed all the safe recruitment checks.

Are services effective?

We do not rate effective for this type of service:

- The service provided care and treatment based on national guidance and evidence of its effectiveness. Managers checked to make sure staff followed guidance.
- The service had facilities for patients to help themselves to a choice of hot drinks or water, in the main waiting room. The service could offer people appointment times to reflect their needs and preferences if they required fasting or were diabetic.
- Managers monitored the effectiveness of care and used the findings to improve them. They held multi-disciplinary meetings to evaluate images and techniques to improve image quality for the benefit of patients.
- The service made sure staff were competent for their roles. There were systems for managers to check staff professional registrations, appraise their work and provide support.
- Staff understood how and when to assess whether a patient had the capacity to make decisions about their care.

Are services caring?

We rated it as **Good** because:

- Staff cared for patients with compassion. Feedback from patients confirmed that staff treated them well and with kindness.
- Staff provided emotional support to patients to minimise their distress. For example, if they were anxious about having an MRI scan.
- Staff involved patients and those close to them in decisions about their care and treatment. Patients said staff explained the procedure and a radiographer said they did this so patients were reassured.

Good



Are services responsive?

We rated it as **Good** because:

Good



Summary of this inspection

- The service planned and provided services in a way that met the needs of local people. The environment was appropriate and comfortable for patients, including those with mobility needs. Patients we spoke with were positive about the environment and organisation of the service.
- The service arranged appointment times to suit patients.
- The service supported carers to be with patients for reassurance during an X-ray, using a recognised consent procedure with carers to explain the risks of ionising radiation exposure.
- People accessed the service when they needed it. The service was relatively new and there were short waiting times from referral to scan. Patients could often have a referral and scan the same day, within 24 hours or when it was most convenient for them.
- The service had not received any concerns or complaints since opening in July 2018 but staff recognised the importance of taking complaints seriously and learning from them.

Are services well-led?

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

- There was not a systematic approach for reviewing all aspects of quality and safety. The governance arrangements were not clear and the provider had not evaluated policies, such as recruitment and infection prevention and control policies, against practice.
- The provider had not developed a means of identifying and managing risks to the service going forward.
- The provider's policies did not always reflect the specific activities carried out by the service. For example, the accident and incident reporting policy and procedure did not refer to accidental or unintended exposure to radiation or how to report such incidents.

However, we also found the following areas of good practice:

- The service had a vision for what it wanted to achieve and workable plans to turn it into action. Service leads were involved in developing these plans.
- The manager and service leads promoted a positive culture that supported and valued staff, creating a sense of common purpose based on shared values. Staff reported they worked well together and trusted and respected each other.
- There was a strong emphasis on patient-centred care. Staff promoted openness and honesty and understood how to apply the duty of candour.
- There were systems to manage known, existing risks.

Requires improvement



Summary of this inspection

- The service collected, analysed, managed and used information well to support all its activities, using secure electronic systems with security safeguards.
- The service had engaged with local organisations to plan services, and had plans to seek patient feedback once more established.
- The service was committed to improving services by learning from when things went well or wrong, promoting training and innovation. The service held regular learning meetings involving the radiographers, radiologists and orthopaedic surgeons to improve the quality of their images.

Detailed findings from this inspection

Mental Capacity Act and Deprivation of Liberty Safeguards

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

Overview of ratings

Our ratings for this location are:

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

Diagnostic imaging

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

Are diagnostic imaging services safe?

Good 

This was the first time this service has been rated. We rated it as **good**.

Mandatory training

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

- The provider had a contract with an external company to provide e-learning courses, some face to face training modules and training alerts. They provided all the mandatory training requirements, including manual handling, safeguarding adults and children, infection prevention and control, health and safety, data protection and equality and diversity.
- All staff had either completed their annual mandatory training or were progressing with the on-line courses prior to their annual appraisals in January and February 2019.
- The local rules and MRI operating procedures showed staff with a clinical role had completed training in the safe use of equipment and understood risks associated with the use of the equipment.
- New members of staff were required to complete an induction, with a six-month sign-off check.
- Staff said they felt supported to complete their training and appreciated they could access it on line when it was convenient for them.

Safeguarding

Staff understood how to protect patients from abuse and the service worked well with other agencies to do so. Staff had training on how to recognise and report abuse and they knew how to apply it.

- The registered manager and senior radiographer had both completed adult and child safeguarding training to level 3, and the registered manager was the safeguarding lead for the service.
- Staff had access to safeguarding training from a suite of on-line courses.
- There was information on what constitutes abuse, how to report concerns and relevant contact details on the service's information board in the main waiting room. This meant that patients and visitors also had access to safeguarding information and guidance.
- The provider's policy on safeguarding included guidance and procedures for both vulnerable adult and child safeguarding. It covered topics such as female genital mutilation and mental capacity assessments.
- The staff had not identified concerns that had prompted them to make a referral, whilst working at this service. Those we spoke with could describe examples of observations that would raise their concerns, such as evidence of non-accidental injuries, and how they would report them.

Cleanliness, infection control and hygiene

The service controlled infection risk well.

- Staff generally kept the premises clean. They used control measures to prevent the spread of infection.

Diagnostic imaging

- The senior nurse was the lead for infection control and they planned to carry out an annual infection control audit during January and February 2019.
- The lead for infection prevention and control had completed a hand hygiene audit. There had been no issues to address with staff practices, but the audit had identified two taps with missing diffusers, which the registered manager had arranged to fix.
- All staff had completed provider training in infection prevention and control within the past year, which included hand washing techniques.
- Staff were seen to be bare below the elbow, which is good infection prevention and control practice.
- The infection control policy stated that hand washing posters were displayed at hand basins, however this was not the case.
- The unit appeared clean. There were clinical wipes available to clean the equipment between patients and disposable paper covers for couches and hand gel. There were hand basins, paper towels and waste bins in each consulting and diagnostic scanning room.
- An external cleaning company cleaned the floors, surfaces and environment. The registered manager received weekly feedback on the quality of service they provided.
- The service had a laundry contract for pillow cases and gowns. Clean items were stored in a dedicated cupboard, separate from items to be laundered, to avoid the risk of cross contamination.
- Patients said the environment was clean and they had seen the radiographer using the wipes and hand gel. They said the radiographer used personal protective equipment, such as gloves, and disposed of them appropriately.
- Radiographers were responsible for cleaning the diagnostic equipment. There was a list of cleaning duties on the white board, however the service did not create cleaning checklists, to enable staff to monitor any trends or omissions, nor any system for labelling when equipment was clean. Although almost all areas were clean and dust free, we found the top of the MRI equipment was dusty, indicating it had not been cleaned for some time.
- There was a locked room for cleaning materials and items were stored on shelves.
- There were disposable curtains for patient dignity in the consulting rooms. These were not dated to show when they had been fitted, to highlight when they were due to be replaced. However, this was a service that had only been active for five months and the curtains appeared clean and in a good condition.
- There had been no incidences of healthcare acquired infections at the service.

Environment and equipment

The service had suitable premises and equipment and looked after them well.

- The premises were new and designed for purpose, to promote safety, dignity and access. The service was in a business park with adjacent parking.
- The reception desk was close to the main entrance, and slightly to one side of the ground floor waiting area. There was adequate seating capacity for patients and their relatives. There was a smaller waiting room on the first floor, opposite the nurses' station, for patients who had already checked in.
- There were toilets on the ground and first floor, both designed for wheelchair access. The upstairs toilet had been assessed by the fire service as a 'refuge area' which meant it was the place where people, who could not use the stairs, could stay safely for up to two hours if there was a fire. There was an intercom in the room to enable the fire service and others to communicate with people in an emergency.
- Access from the main waiting area to the diagnostic imaging areas on the ground floor was via a secured door, to prevent unauthorised access. There was another secured door between the staircase and the upstairs clinical area. Only staff with the correct passes could open these doors, and radiography staff escorted patients from the waiting areas to the scanning areas.
- The key to the MRI room was left in the door during the day and secured within the MRI control room

Diagnostic imaging

when not in use and at night. This approach had been assessed as safe as patients were only in this area when accompanied by radiographers, due to the secure entrance from the waiting area.

- There were two patient changing rooms on the ground floor, with lockers and laundry baskets, within the secured area. Radiographers escorted patients to changing rooms and then to the scanning/imaging rooms.
- Upstairs, staff could create curtained changing areas within the DEXA and ultrasound rooms for patients to change in private.
- There were warning lights outside the doors to the DEXA and X-ray rooms. These warned people of the risks of radiation and lit up when the equipment was in use.
- All the equipment was new, and had been fully tested and commissioned. The X-ray and DEXA equipment had passed critical examinations for radiation safety and acceptance testing, under the Ionising Radiations Regulations 2017 (IRR 2017) by the Medical Physics Expert.
- The service had up to date local rules for the DEXA and X-ray equipment, describing safe operating procedures in line with the Ionising Radiation (Medical Exposure) Regulations (IR(ME)R) guidance.
- The service had lead aprons available for staff and people accompanying patients for X-ray imaging. Staff checked these for damage and would remove any from service if they found faults.
- The radiation protection advisor (RPA) had attended the service prior to the installation of equipment and they had provided guidance on colour coding the flooring to define safe areas for staff and patients within the DEXA and X-ray rooms.
- Staff involved in delivering ionising radiation carried dosimeters to monitor their exposure to radiation. As a new service, the RPA and MPE had completed a radiation survey of the building before and after commissioning the DEXA and X-ray equipment. The service was also carrying out a two-month test of radiation levels throughout the premises, with dosimeters located on various parts of the building. The provider used an independent company for the analysis and reporting of the dosimeters data.
- The medical physics expert had completed acceptance testing of the new MRI equipment in May 2018, and the equipment was under the manufacturer's warranty until May 2019.
- The control room for the MRI unit allowed the radiographer to have a full view of the patient and the equipment. There was an intercom system so the patient and radiographer could communicate, both into the room and through the patient's headphones.
- The registered manager (RM) had prepared instructions for the MRI scanner, which staff who had access to the area had signed to show they had read and understood. There was an appointed safety advisor for the MRI scanner and the RM took the role of responsible person for this equipment. These instructions outlined the systems of work, hazards, how to respond to a patient in cardiac arrest or a fire, and referenced the Health and Safety at Work Act 1974.
- All equipment in the MRI room was labelled to show it was MR-safe, in line with Medicines and Healthcare Products Regulatory Agency (MHRA) recommendations. There was a MR-safe patient trolley to be used in an emergency to transport a patient out of the room. The service also had an MR-safe set of ladders and wheelchair. The provider had also created defined safe areas for the MRI unit.
- There were daily quality assurance checks for the MRI unit, as well as checks of the humidity of the room, to ensure it was set up to operate safely.
- The scanners had inbuilt automatic safety testing systems, and the service kept records to show the equipment was safe to use. These were start up checks as well as regular (roughly weekly) checks.
- Scanning equipment was still under the manufacturer's warranty at the time of our inspection, and the manufacturers provided prompt responses

Diagnostic imaging

when necessary. For example, there had been a fault in the MRI electricity supply which meant the unit needed a new regulator, which was installed under warranty.

- The service had adult and child resuscitation equipment, stored next to the reception desk. The contents were checked against a contents list and all items were in date. The registered manager showed us how they would ensure safe oxygen flow. There was also an automated external defibrillator (AED) available, which staff checked was charged and ready for use in an emergency.
- Staff checked the first aid kit each month and signed the checklist.
- The service had not signed up to NHS patient safety alerts. The registered manager said they would investigate how best to receive this information.
- The provider had undertaken the assessment and reviews of their activities, under the Control of Substances Hazardous to Health Regulations 2002 (COSHH), and these assessments were recorded and kept on file. The provider had equipment for cleaning body fluid spills.
- The service had contracts with external organisations for the monthly removal of clinical waste, legionella water testing and for servicing the lift.

Assessing and responding to patient risk

Staff reviewed and updated risk assessments for each patient, using the referral forms and tailored patient questionnaires.

- Staff kept clear records of patients' risk assessments. Patients attended for a scan with an Opus Diagnostic referral form, which they often brought with them as hard copy. These detailed the patients' clinical information, their names, addresses, dates of birth and phone numbers, as well as the type of scan required and the area of the body to be scanned. The referral forms included the referring clinician's details and where to report the imaging results.
- The Opus Diagnostic referral forms prompted the referrer to record pregnancy risks and patients were asked to sign that to the best of their knowledge they were not pregnant. The service did not accept patients for imaging if they said they were pregnant.
- The service accepted referrals for scans from medical staff and approved physiotherapists, who had attended educational evenings on the application of the MRI equipment to be approved non-medical health professional referrers. The service was considering creating a training course for musculoskeletal physiotherapists, to extend their list of approved non-medical health professional referrers.
- The staff followed processes to ensure the right person received the right radiological imaging at the right time. Staff verbally checked each patient's identity, medical history and pregnancy risk before they prepared them for their scan. The verbal risk assessment process included checking that imaging was needed and appropriate.
- Staff assessed patient risks and developed risk management plans in line with national guidance. Patients completed safety questionnaires each time they attended, in relation to their medical history and medication. For example, for an MRI scan, patients were asked about a range of different types of implants, surgery, body piercing and treatments that might affect the quality and safety of the procedure. Staff also noted patient's height and weight to optimise exposure levels. The radiographer gave an example of when they had requested further information about a patient's brain clip, before progressing an MRI scan.
- Staff undertook routine practice drills for the safe removal of a collapsed patient from the MRI room. This was part of their monthly safety testing procedures.
- The service had local rules for the X-ray and DEXA procedures, setting out the safe operating arrangements for working with ionising radiation, in line with IR(ME)R 2017. The registered manager was the service's radiation protection supervisor (RPS) and the service had appointed an accredited, external radiation protection advisor (RPA) and medical

Diagnostic imaging

physics expert (MPE). The local rules outlined instructions for the safe use of ionising radiation equipment, including the access controls, use of protective equipment and radiation monitoring.

- The service displayed national and local dose reference levels, to minimise the risk of radiation overexposure. Radiographers recorded exposures on patient records within their picture archiving and communication system (PACS).
- The radiographers said they escalated any unexpected or significant findings from image reports to patients' referrers.
- Staff said they accepted children for MRI scans if they demonstrated they understood the procedure. They always planned for a longer appointment time, for discussion and explanations and had not treated children under eight years of age.

Nurse and radiographer staffing

The service had enough staff with the right qualifications, skills, training and experience to keep people safe from avoidable harm and to provide the right care and treatment.

- The service ensured there were always at least two staff members on site during working hours, to support the needs of patients and maintain staff safety.
- The service employed one full time receptionist and a further receptionist on a zero-hours contract to provide cover. As well as the manager, there were three further radiographers, one full time and two others (one part-time and one on a zero-hours contract). This enabled the staff to provide adequate cover for leave and sickness. In addition, the service had recently employed a radiographic department assistant. The service also employed six nurses (under different contractual arrangements), who supported the orthopaedic consultants when they held their consultation clinics on site.
- The service did not use agency staff, but had used bank nursing and receptionist staff for 10 shifts during the three-month period to 4 October 2018.
- A radiography department assistant had started work at the service in the month before our inspection visit.

They had been recruited to the service through personal recommendation from staff. Neither their Disclosure and Barring Service (DBS) check nor their references had been obtained. A DBS check shows whether an individual has a criminal record, caution, warning or conviction and helps employers make safe recruitment decisions. This meant the service had not received the assurance that the employee was suitable and safe to work with children and young people. This staff member had completed an induction on the safe use of equipment and was receiving training by the receptionist on the day we visited. The registered manager confirmed the staff member would remain in a shadowing role until they had received the necessary assurances.

- We saw the service had checked that all nursing staff and radiographers had valid professional registrations.

Medical staffing

The service had access to enough medical staff with the right qualifications, skills, training and experience to keep people safe from avoidable harm and to provide the right care and treatment. The medical staff were not directly employed by the service.

- The service did not employ medical staff. Most investors in the company were orthopaedic consultants, who made referrals to Opus Diagnostics for scans.
- The service had contracts with three radiologists, to provide reporting services as self-employed consultants under practicing privileges. They provided evidence of their training (including mandatory training), recent appraisals, medical indemnity insurance and professional registrations.
- The service checked medical staff had valid professional registrations.

Records

- **Staff kept detailed records of patients' care and treatment.** Records were clear, up-to-date and easily available to all staff providing care.
- The provider had a secure electronic records and imaging archiving system to enable staff and referrers to access records using their personal security

Diagnostic imaging

passwords. The service used an encrypted system for sharing emails and documents with referrers, for data security. The service scanned any paper records, such as patient medical questionnaires, into their electronic records. Staff then shredded the paper copies.

- The service had a recognised picture archiving and communication system (PACS) and radiology information system (RIS). This is a networked software system for managing medical images and reports.
- We saw the referral forms were clearly completed, but one MRI referral did not include the referrer's registration details.
- The MRI records showed exposure levels and completed questionnaires with patient details including their height and weight.
- The DEXA records showed radiographers recorded patient identity, height and weight. The reports included the results summary, a 10-year fracture risk assessment and a graph illustrating the patient's bone density score/osteoporosis risk. The reports detailed the referring physician, the equipment used and an image showing the part of body scanned.
- Referrers shared information relating to the diagnostic test and any treatment plan with the patients' GPs. The registered manager explained they could send copies to GPs if the referrer requested this.

Medicines

The service followed best practice when prescribing, giving, recording and storing medicines.

- The service had appointed a nurse as lead for medicine management, and had a contract with a local pharmacy for the supply of medicines.
- Only visiting consultant orthopaedic surgeons administered medicines, and the service had a private prescription pad to use if necessary. There had been no medicines prescribed at the time of our visit. Nurses and radiographers did not administer medicines.
- The service did not use MRI contrast agents or controlled drugs. There was no sedation offered.

- A small range of medicines were kept on site for pain relief. These medicines were stored securely and the keys were either held by the lead nurse or locked away.
- Medical consumables were stored in organised cupboards in the nurses' station and all items were in date.
- The storage temperature was monitored through the environmental control system, between 17 and 23 degrees Celsius, depending on the season. There was no medicine fridge and the service did not store medicines that needed refrigeration.
- The sharps bins were correctly assembled and stored safely in locked rooms.
- At the time of the inspection, the service did not offer any invasive procedures. The service was evaluating the possibility of adding a new procedure that would involve invasive procedures. The registered manager was assessing the implications of this, in terms of the safe use of medicines, staff training, access to emergency medicines and transport and pharmacy support.
- We saw two out of date British National Formulary books and an out of date medical device that had been removed from service, in the nurses' station. The registered manager arranged for these to be disposed of during our inspection.

Incidents

- **The service had systems to manage patient safety incidents.** There had been no incidents relating to patient safety since the service had opened. However, staff understood how to recognise and report an incident. For example, the registered manager had experience in incident management, and knew how to investigate and learn from incidents as well as the importance of apologising and supporting patients.
- The provider's accident and incident reporting policy and procedure did not refer to, or include, reporting guidance on the type of incidents that might occur in this type of service, such as accidental or unintended exposure to radiation. The policy did not outline the duties and guidance on reporting and investigating incidents, as stated within the Ionising Radiation (Medical Exposure) Regulations 2017 (IR(ME)R 2017).

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- Although IR(ME)R was not referenced within in the policy, staff understood what they would report as incidents, for example wrong body part scan. The registered manager was aware of the types of incidents that must be reported to the Care Quality Commission and other bodies.
- The accident and incident reporting policy referred to the duty of candour, which is the requirement for staff to be open and honest to patients following an incident. It also outlined procedures for the Reporting of Injuries, Diseases and Dangerous Occurrences Regulations 2013 (RIDDOR). The policy included template forms to record both patient and employee accidents/incidents.
- The provider had a reporting system for recording and reporting patient safety incidents and near misses. The service had not reported any incidents since opening in July 2018.

Are diagnostic imaging services effective?

We do not rate effective for this type of service.

Evidence-based care and treatment

The service provided care and treatment based on national guidance and evidence of its effectiveness.

Managers checked to make sure staff followed guidance.

- The service based its policies and procedures for the X-ray and DEXA equipment on the Ionising Radiation (Medical Exposure) Regulations 2017 (IR(ME)R 2017). The local rules were up to date and reflected the equipment, staff and practices at this location.
- The service applied the Public Health England guidance on National Diagnostic Reference Levels when setting their local diagnostic reference levels (DRLs). These were based on national DRLs for adults and children.
- For the X-ray, the service had received one recall, where the referring orthopaedic consultant had requested an additional scan to see another disc on the lumbar spine. There had been no returns for poor quality images.

- The provider's policies and procedures relating to the use of radiation were subject to review by the radiation protection advisor and the medical physics expert, in line with IR(ME)R 2017 requirements.
- The provider had created operating procedures for the MRI equipment, along similar lines to the local rules for ionising radiation equipment. The provider was working closely with the manufacturers to optimise the quality of images using this equipment, which was a new type of MRI equipment, with higher resolution possibilities. The equipment was under warranty at the time of the inspection, and a MRI safety expert would be appointed once the warranty expired mid-2019.
- The service planned for the Radiation Protection Advisor to carry out an annual audit against the IR(ME)R 2017 requirements in May 2019.

Nutrition and hydration

- **The service had facilities for patients to help themselves to hot or cold drinks.** There was a counter with a drinks machine in the main waiting room where patients could help themselves to a choice of hot drinks or water.
- The service offered people appointment times to reflect their needs and preferences if they were fasting or were diabetic.

Pain relief

The service provided diagnostic assessments of patients who might be experiencing pain.

- The consultants asked patients about their pain as part of their assessment process to identify areas for a diagnostic scan. They administered medicines for pain relief such as anti-inflammatory medicines, and recorded this in the patient records.
- The radiographers said they assisted patients into a comfortable position for their scans, to minimise aggravating any pain.

Patient outcomes

Managers monitored the effectiveness of care and used the findings to improve them.

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- The provider had purchased a 3T MRI scanner, which meant they could generate better images than those from conventional 1.5T scanners, and reduce the likelihood for needing repeat scans. It was also faster, and patients experienced shorter examination times and reduced risks from claustrophobia. The service was working with the manufacturers to optimise the scans for different parts of the body.
- The radiologists audited each other's reports, with 10% of all reports read by a second radiologist, under specific authorisation. This enabled radiologists to review and check the quality of reports.
- As a result of audit and review, the radiologists had set up image quality meetings, to discuss how they could improve specific scans using the new MRI equipment. For example, they shared learning on how best to identify tears. The higher resolution of the 3T MRI allowed radiologists to identify small lesions and anatomical structures, which improved diagnoses and patient outcomes.
- For the DEXA images, the service relied on referrers to assess the frequency of repeating bone density scans. The National Osteoporosis Society recommends follow up scans after two or more years, to provide a realistic assessment of change in bone density.
- All reports we viewed, including X-ray images, were of high quality. The service aimed to provide the highest possible quality images from their new equipment.
- The registered manager gave 360-degree feedback to the consultants, as part of their appraisal process. A consultant radiologist carried out the appraisal for the registered manager.
- The registered manager was the radiation protection supervisor. They had completed radiation protection supervisor training in 2018.
- Records showed relevant staff were up to date with their IR(ME)R training, as well as training in the MRI. Clerical staff were trained in the use of the different information systems.
- The provider had contracted training and development services from an external company, and staff had individual access to mandatory training modules. Staff induction included training in infection prevention and control, health and safety, fire safety, safeguarding, information governance, confidentiality and vision and values.
- Staff said they were supported to develop their skills and experiences.

Multidisciplinary working

Staff worked together as a team to benefit patients.

- Staff at the service worked closely with the referrers to enable patients to have a prompt diagnosis and promote a seamless treatment pathway. If they identified concerns from scans they escalated them to the referrer.
- The monthly image quality meetings facilitated shared learning between the consultant surgeons, radiologists and radiographers, which all staff found informative. They had enabled consultants and radiographers to improve their requests and techniques to optimise the imaging.
- The administration staff felt part of the team and supported the service by developing and improving the administrative services.
- The registered manager outlined plans for supporting new medical and non-medical referrers to use their services, by providing training in the types of diagnostic imaging they offered.

Seven-day services

Competent staff

The service made sure staff were competent for their roles.

- Managers appraised staff's work performance and provided support.
- All health care staff were registered with their appropriate professional bodies. The service ensured it received evidence from medical practitioners of their appraisals and registrations.
- The registered manager carried out the appraisals of the senior radiographers, nurse and receptionist and these staff appraised staff reporting to them. Staff had received their pre-appraisal forms at the time of the inspection and appraisals had been scheduled for late January 2019.

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The service was not established to offer a seven-day or emergency service, but could offer flexible appointment times.

- The service was operational Monday to Friday, normal working hours but these could be extended to support specific patient requests.
- There was no waiting list and patients were given the first available appointment on a date that was most convenient for them. The patients we spoke with all said they were offered appointments quickly, sometimes the same day.

Health promotion

- The service did not provide a role in health promotion.

Consent and Mental Capacity Act

Staff understood how and when to assess whether a patient had the capacity to make decisions about their care.

- Staff understood their responsibility to gain consent from patients. They recognised and respected a patient's choice, for example if they chose not to have any treatment or imaging when they arrived for their appointment.
- Staff gave patients sufficient time to consider their options before giving consent. They explained that patients sometimes needed reassurance and additional time before consenting to have an MRI scan, for example if they were claustrophobic. One patient had gone away and returned at a later date for their scan.
- The provider's referral forms had a section for patients to sign consent for the scanning procedure, as well as consent for the service to store their information.
- The radiographers explained how they talked through procedures with patients, including children and young people and those with cognitive impairment, to ensure they gave informed consent. The service treated children and young people with sports injuries, who could consent to having a scan taken.
- All patients confirmed they had been asked for, and had given, their consent for the procedure they had attended for.

- Staff were aware about their responsibility in relation to patients who lacked mental capacity. They said they would normally receive information in the referral about a patient's capacity and they understood their role in complying with the Mental Capacity Act 2005.

Are diagnostic imaging services caring?

Good 

This was the first time this service has been rated. We rated it as **good**.

Compassionate care

Staff cared for patients with compassion.

- Feedback from patients confirmed that staff treated them well and with kindness.
- Radiographers discussed patients' questionnaires with them in the scanning areas, not in the waiting rooms, so they could speak with patients in private.
- Patients said the staff were consistently helpful and friendly. One patient said the receptionist called before their appointment to check they knew the way to the service which they appreciated.
- Patients also told us the radiographers introduced themselves, which helped them feel reassured.

Emotional support

Staff provided emotional support to patients to minimise their distress.

- Staff commented that patients sometimes experienced anxiety about having an MRI, but they were proud to feed back that none of their patients had ever refused their appointment. They felt they could offer them time and reassurance, and the opportunity to view the set up and environment.
- The service displayed notices in their reception and waiting areas offering patients a chaperone should they wish one.

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- They also offered patients a carer to be present during an X-ray, explaining they would experience exposure to radiation, and outlining the risks. This meant patients did not have to be alone for their scans if they preferred a friend or relative with them.

Understanding and involvement of patients and those close to them

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

- Patients said staff explained the procedure, double checked what scan they were having and checked their identity thoroughly, including their date of birth and address. A patient attending for an MRI scan said the radiographer clearly explained the risks associated with metal and reviewed their questionnaire in detail with them, discussing any potential risks. They appreciated this level of care.
- Patients said they were invited to ask questions and so they understood what they were asked to give consent for. One person said they looked at the brochures available in the waiting room, explaining the different types of scans on offer, and they felt these were helpful.

Are diagnostic imaging services responsive?

Good 

This was the first time this service has been rated. We rated it as **good**.

Service delivery to meet the needs of local people

The service planned and provided services in a way that met the needs of local people.

- The environment was appropriate and comfortable for patients, and patients we spoke with were positive about the environment and organisation of the service.
- At the design and build stage, the service had involved a local disability group to visit and advise on access and safety features.

- The service had a website, however at the time of the inspection this had been taken down for an update.
- The registered manager explained the service aimed to add new services, for example to extend the use of the DEXA and MRI scanning equipment. This was in consultation with local GPs, physiotherapists, consultants as well as the investors. The service also considered tendering for NHS contracts.

Meeting people's individual needs

The service took account of patients' individual needs and put them at the heart of services.

- The service could arrange appointments to suit the specific needs of patients, for example taking into consideration their work or school commitments or travel constraints.
- The service was accessible to people with mobility constraints. There was parking next to the service, and there was wheelchair access throughout the patient areas. The reception desk had a section where the counter was lowered to enable staff to greet patients in wheelchairs.
- The premises supported patient privacy and dignity. The consulting rooms had curtains, to create changing areas, and privacy windows with additional blinds. The receptionist had recognised there was a risk of patients being overheard at reception, and the service had installed music, to promote privacy.
- The waiting room was furnished with different types of chairs, including some with arms to assist people standing up.
- The service supported patients to have a carer with them for an X-ray. They used the IR(ME)R 'Comforters and Carers' procedure, whereby staff explained the risks of ionising radiation exposure to the carer and asked them to sign consent. This meant patients could have a relative or friend with them during a procedure for reassurance. The service used the same approach for patients having an MRI scan.
- Staff explained they planned longer appointment times for patients who they anticipated might need additional support, such as for children and patients with a learning disability or a significant physical disability. A radiographer outlined the support they

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had given to a patient with a learning disability, where they had used the longer appointment time, to ensure the patient had time to consider and understand the procedure.

- Staff invited patients to play their own playlists if they had suitable technology, or they could listen to the radio or other music during their MRI procedure.
- The service had MR-safe equipment, such as a wheelchair and a walking frame, which could be used for patients who needed mobility assistance.
- The service accessed translation services if required, but at the time of the inspection staff said they had not had a need to use them.
- The service provided patients with their own CD copy of their scan, before they left the service. This meant the patient could access information at a later date, without having to ask the referrer for a copy.

Access and flow

People accessed the service when they needed it.

- The service was relatively new and there were short or no waiting times from referral to scan, depending on patient choice.
- The service did not have a waiting list. Patients could often have a referral and scan the same day, within 24 hours or when it was most convenient for them.
- The service could open early if requested, to provide scans for patients before or after the normal working day.
- Patients we spoke with were pleased they had been offered appointments promptly. They also commented that it was easy to park at this location.
- Having a radiologist on site meant the service often reported scans the same day, sending reports to the consultant's secretary. They reported all scans within five days, although the service did not collect data on this performance.
- The service had experienced a fault in the MRI electricity supply, requiring the installation of a new regulator. As the MRI equipment was inoperative for 10

days, staff arranged for any booked patients to either have their scan done at an alternative service nearby or wait until the equipment was repaired, whichever met their specific needs.

Learning from complaints and concerns

The service had not received any concerns or complaints since opening in July 2018 but staff recognised the importance of taking complaints seriously and learning from them.

- Patients we spoke with told us they were pleased with their care and treatment and had no reason to make a complaint.
- The provider had a policy for managing complaints, which included timescales for acknowledging a complaint (three days) and responding (10 days, or advised of an estimated date if necessary). The policy also outlined the duty of candour.
- There was information on how to make a complaint available for patients to refer to in reception.
- The service had not received a complaint since opening in July 2018.

Are diagnostic imaging services well-led?

Requires improvement 

This was the first time this service has been rated. We rated it as **requires improvement**.

Leadership

The registered manager and senior radiographer had the right skills and abilities to run a service providing high-quality sustainable care.

- The registered manager was an experienced radiographer and although this was a new service, they had over 10 years of experience in managing other diagnostic imaging services.
- Staff said the registered manager was very accessible if they wanted advice or to make suggestions. They kept them informed of plans and developments for the service.

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- The registered manager had a good understanding of how the business was projected to develop and recognised their role in ensuring the service developed the right systems to support any new developments.
- The service displayed the location and manager CQC certificates in reception, as well evidence of employer liability insurance.

Vision and strategy

The service had a vision for what it wanted to achieve and workable plans to turn it into action. Service managers were involved in developing these plans.

- The provider, Berkshire Medical and Imaging Centre Ltd, opened this service in Ascot in July 2018, under the trading name of Opus Diagnostics. The investors included a group of consultants, mostly orthopaedic surgeons, with a strategy to develop the imaging services. The provider had a clear business and financial strategy, and had purchased high specification scanning equipment.
- The provider's mission statement, from their statement of purpose, was to 'give our best to our patients' and to 'offer our patients an extremely high level of clinical excellence'.
- In support of this, staff were committed to providing good patient care and the service offered training to potential new referrers on how best to make an effective, safe referral.

Culture

Service leaders and the manager promoted a positive culture that supported and valued staff, creating a sense of common purpose based on shared values.

- Staff reported their team worked well together and trusted and respected each other. Many had worked together previously and said they encouraged and supported each other.
- There was a strong emphasis on patient-centred care. Staff promoted openness and honesty and understood how to apply the duty of candour.

- There was an appraisal process in place that was two-way and encouraged staff development.

Governance

The service had set up meetings for improving image quality, but there was not a systematic approach for reviewing all aspects of quality and safety.

- Since opening, the service had held two governance meetings since opening. These were attended by investors, radiologists and radiographers.
- Minutes of the meetings showed although there was a focus on quality and safety, the meetings did not consistently cover all aspects of the service's governance arrangements. The minutes of the first meeting showed discussions related to resuscitation equipment, medicines, staffing and GMC registrations. However, the second meeting, in December 2018, was more focused on image quality. The attendees agreed to set up monthly meetings to discuss the quality of imaging, but there was no emphasis placed on other matters relating to the running of the service. There was no set meeting agenda and a lack of distinction between clinical audit and governance meetings.
- The meeting minutes indicated that roles and responsibilities for governance were not clearly defined. It was not clear from the minutes who chaired the meetings and who had responsibilities for different aspects of quality and safety for the service.
- Although the provider had a clinical governance policy, the document was not dated to show when it had last been reviewed, and it did not provide guidance on the frequency of meetings or their content.
- The service had had a contract for support with policies and compliance with regulations. However, we found that policies were not always aligned to the service, to reflect its specific activities and risks. For example, the accident and incident policy did not refer to the types of incidents associated with ionising radiation and how to report them.
- The service had not evaluated policies and practices. For example, recruitment procedures had not been adhered to.

Managing risks, issues and performance

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- **There were systems to manage known, existing risks. The service had not developed a formal system to identify new risks, plan to eliminate or reduce them, and monitor them on a regular basis.**
- The registered manager had undertaken risk assessments and put in place management plans and procedures for key risks associated with setting up the service. The provider had not set up a formalised system, to capture risks and record their management and mitigations identified during the ongoing running of the service. This was a topic the registered manager started to explore after the inspection.
- There were systems to manage known, existing risks. For example, the service had weekly fire alarm tests and had carried out a fire drill practice. A fire officer had visited the site, both before installing the equipment and after, and the service understood not to enter the MRI room in the event of a fire. There was a fire refuge on the first floor, with an intercom system. The fire extinguishers were in date and there was clear signage to show fire exits. The staff had carried out evacuation drills for patients in the MRI unit, using the MRI-safe trolley. Equipment in the MRI room was marked MR-safe and there was appropriate signage in place to alert people to the risks associated magnetism.
- There were always at least two staff on site when the service was open, to minimise any risk to staff from lone working. When the registered manager worked on site alone they ensured the exterior door was locked.
- Patients were invited to have chaperones, for example if they had appointments with staff of a different gender.
- The service did not have a generator to provide electrical backup, but equipment had inbuilt batteries to enable the practitioners to finish their scan and save images. This was part of the equipment safety features.
- The provider had a business continuity plan. When there had been a power failure for the MRI, the situation was managed safely, quickly and with due concern for patients' needs.

Managing information

- **The service collected, analysed, managed and used information well to support all its activities, using secure electronic systems with security safeguards.**
- The provider had set up a system of electronic patient records. Staff scanned any paper records into the patient records, and destroyed the paper copy.
- Patients consented for the service to store their records, with access by the referring clinician. This was part of their signed agreement within the referral. The registered manager had commissioned an agency to carry out an assessment of their processes and they were shown to be compliant with the 2018 (GDPR 2018).
- The service had adopted a secure, cloud-based information storage system, where the reports and images were accessible only to authorised persons. The service had its own integrated picture archiving and communication system (PACS) and radiology information system (RIS), where consultants could view their own images and reports securely. The service had also signed up to access the NHS PACS and RIS systems.

Engagement

- **The service engaged with staff and local organisations to plan services, and collaborated with partner organisations effectively.**
- The provider had engaged with the local disability group to help with the design of the building. It has followed the advice of the group to create a fire refuge on the first floor and to install an appropriate lift.
- The provider engaged with insurance companies to ensure they worked effectively in the provision of services.
- The service had not carried out a patient survey since opening in July 2018. There were forms patients could complete to give feedback about their experiences, but these had not been actively promoted. The service had however received some thank-you responses.

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- The website had been taken down at the time of the inspection, to be reviewed and improved, and the registered manager said they planned to carry out a survey via their website once it was re-activated in 2019.
- Staff were encouraged to give feedback and were listened to. It was through staff suggestions that the service had recognised the need to install a music system to promote privacy at the reception desk.

Learning, continuous improvement and innovation

- **The service was committed to improving services by learning from when things went well or wrong, promoting training and innovation.**
- The service held regular learning meetings involving the radiographers, radiologists and orthopaedic surgeons to improve the quality of their scans. They had also involved advisors from the equipment manufacturers with the aim of optimising the potential of the diagnostic scanners.

Outstanding practice and areas for improvement

Areas for improvement

Action the provider **MUST** take to improve

- The provider must set up governance systems to ensure that risks are identified, quality and safety is reviewed regularly and practices and policies are relevant and regularly reviewed.

Action the provider **SHOULD** take to improve

- The provider should take steps to establish a way of monitoring cleaning to enable them to have assurance that all parts of the premises are kept clean.
- The provider should set up a system to ensure that recruitment checks are carried out so they have assurance that new employees are safe and suitable.

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 17 HSCA (RA) Regulations 2014 Good governance Systems or processes must be established and operated effectively to assess, monitor and improve the quality and safety of the services, to identify and manage risks and to evaluate the governance systems. Regulation 17 (1)(2)(a)(b)(f)