

Leeds PET-CT Centre

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?

Requires improvement



Are services effective?

Not sufficient evidence to rate



Are services caring?

Good



Are services responsive?

Good



Are services well-led?

Good



Overall summary

Leeds PET-CT Centre is operated by Alliance Medical Limited. The service is based in a purpose-built facility within the nuclear medicine department of the Bexley Wing, St James University Hospital, Leeds.

PET-CT was a directly commissioned service within NHS England. The service has a service level agreement in place with the NHS Trust to deliver positron emission tomography (PET) scanning services to West Yorkshire via NHS England and Leeds Teaching Hospitals Trust, taking

referrals for some specialist scans from as far away as Scarborough. Adult and children attend the centre; however, only NHS based staff undertook scans on children.

Positron emission tomography-computed tomography, is known as PET-CT. This nuclear medicine technique combined, in a single gantry, a PET scanner and an x-ray computed tomography (CT) scanner. Sequential images were obtained from both devices in the same session,

Summary of findings

which were combined into a single superposed image. The scan used a special dye containing radioactive tracers. These tracers were injected into a vein in the arm dependant on what part of the body was being examined.

Service facilities included two hot labs, two scanning rooms, a control room, five injection rooms, a changing room and two hot toilets.

We inspected this service using our comprehensive inspection methodology and carried out an unannounced inspection on 4 December 2019. We also completed staff and patient telephone interviews on the 9 and 11 December 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 the service as **Good** overall.

- Managers had the right skills and abilities to run the service and staff described a positive culture where managers, staff and the multi-disciplinary team worked well together. The service ensured staff were competent with the right qualifications, skills and experience to keep people safe from avoidable harm and to provide the right care and treatment.
Managers appraised staff's work performance as a means of development.
- Staff cared for patients with compassion, provided emotional support to minimise their distress and involved patients and those close to them in decisions about their care and treatment. Feedback from patients confirmed that staff treated them well and with kindness.

- Staff understood how and when to assess whether a patient had the capacity to make decisions about their care. Policies and procedures were implemented when a patient could not give consent.
 - The service systematically improved service quality and safeguarded high standards of care. Patient safety incidents were well managed, and staff recognised incidents and reported them appropriately. Staff of different kinds worked together as a team to benefit patients.
 - The service had suitable premises and equipment and looked after them well.
 - The service collected, analysed, managed and used information well to support all its activities, using secure electronic systems with security safeguards.
 - The service planned and provided services that met and took account of the individual needs of local people. Care and treatment was based on national guidance and evidence of its effectiveness and managers checked that staff followed this guidance. Patients could access the service when they needed it, appointments were prioritised, and additional sessions had been put in place so that patients scans could take place in a timely way. Waiting times from referral to scan were in line with good practice.
 - The service treated concerns and complaints seriously, investigated them, learned lessons from the results, and shared these with all staff.
 - The service engaged well with patients, staff, the public and local organisations to plan and manage appropriate services and collaborated with partner organisations effectively.
- However, we also found the following issues that the service provider needs to improve:
- None of the four eligible staff had completed level two children's safeguarding training.
 - Daily resuscitation equipment checks did not always take place as identified by Alliance Medical Limited.
 - Planned maintenance of the defibrillator did not always take place.
 - The corporate business continuity plan was out of date.

Summary of findings

- Patients did not always sign and date their agreement in relation to the use of their images as a teaching aid.
- Staff did not know how to access service specific information.

Following this inspection, we told the provider that it should and must make improvements, to help the service improve. Details are at the end of the report.

Ann Ford,

Deputy Chief Inspector of Hospitals (North)

Summary of findings

Our judgements about each of the main services

Service	Rating	Summary of each main service
Diagnostic imaging	Good	We rated this service as good overall with ratings of good for caring, responsive and well led. Requires improvement for safe. CQC does not rate effective for diagnostic imaging services. There were areas of good practice, and areas identified where the service should and must improve.

Summary of findings

Contents

Summary of this inspection	Page
Background to Leeds PET-CT Centre	7
Our inspection team	7
Information about Leeds PET-CT Centre	7
The five questions we ask about services and what we found	9

Detailed findings from this inspection

Overview of ratings	12
Outstanding practice	35
Areas for improvement	35
Action we have told the provider to take	36

Good 

Leeds PET-CT Centre

Services we looked at

Diagnostic imaging:

Summary of this inspection

Background to Leeds PET-CT Centre

Leeds PET-CT Centre is operated by Alliance Medical Limited. (AML) The Leeds PET-CT Centre comprised of a purpose-built facility within the nuclear medicine department of the Bexley Wing, St James University Hospital, Leeds.

The service opened in May 2010 and this is a NHS service provided by an independent sector provider. The service was commissioned by five clinical commissioning groups and primarily served the communities of the West Yorkshire and Vale of York regions scanning patients of all ages.

The centre operated under the NHS England national PET contract and had two PET-CT scanners on site which operate from Monday to Saturday 0730 - 1930. Saturday opening may also take place if referral volumes are high. The service also operated a two day turn around scan reporting time.

The service had a registered manager in post since January 2011.

Our inspection team

The team that inspected the service comprised a CQC lead inspector and a specialist advisor with expertise in positron emission tomography-computed tomography services.

Information about Leeds PET-CT Centre

Leeds PET-CT centre is a diagnostic provider for PET-CT scanning services and is registered to provide the following regulated activities:

- Diagnostic and screening procedures.

During the inspection, we visited the positron emission tomography-computed tomography (PET-CT) centre.

The current Alliance Medical Limited (AML) staffing includes: one registered manager, one clinical lead, two PET-CT radiographer / technician, one graduate PET CT radiographer. Two clinical assistants and an administrator. The service had shared staffing with the trust who provided 32 hours of trust radiographer time weekly. The NHS staff all worked within the AML local rules.

We spoke with eight staff which included five radiographers and three technologists at Leeds PET-CT Centre. We spoke with three patients and one relative.

We observed one patient scan, tracked one patients journey and reviewed three sets of patient records.

There were no special reviews or investigations of the centre ongoing by the CQC at any time during the 12 months before this inspection. The service had been inspected three times, and the most recent inspection took place in 30 January 2014 which found that the service was meeting all standards of quality and safety it was inspected against.

Activity (April 2018 to November 2019)

In the reporting period 1 November 2018 to 30 November 2019 5067 scans were undertaken at Leeds PET-CT; of these, 87 were private.

April 2018 to November 2019

Track record on safety

- Zero Never events; these are a 'kind of mistake that should never happen' in the field of medical treatment.
- Zero serious injuries

Summary of this inspection

- One Ionising Radiation (Medical Exposure) Regulations / Ionising Radiation Regulations 2017 reportable incidents.
- Zero deaths
- Clinical incidents 11 low harm, 0 moderate harm, 0 severe harm
- Zero instances of hospital acquired Methicillin – resistant Staphylococcus aureus
- Zero instances of hospital acquired Clostridium Difficille
- Zero instances of hospital acquired Escherichia-Coli
- Three complaints

Services accredited by a national body:

- The service has been accredited by the Quality Standard for Imaging (QSI) since December 2018. QSI was designed to be applied within an imaging service for the purposes of quality improvement. It

articulated the expectations of good imaging, international radiology and teleradiology services. It reflected wide consultation and valuable comments and suggestions received from professional colleagues and relevant UK government agencies and regulatory bodies. The accreditation was ongoing.

- The service was accredited in June 2018 under ISO/ IEC 27001 which formally specified an information security management system (ISMS), a suite of activities concerning the management of information risks called 'information security risks' in the standard. The re-accreditation was due in June 2021.
- The service was accredited in relation to Investors in People which is a standard for people management, offering accreditation to organisations that adhere to the Investors in People Standard. The re-accreditation was due in March 2020.

Summary of this inspection

The five questions we ask about services and what we found

We always ask the following five questions of services.

Are services safe?

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

- Not all eligible staff had completed level two adult safeguarding training. Current training compliance was that 20% of eligible staff had completed level two adults safeguarding training.
- None of the four eligible staff had completed level two children's safeguarding training.
- Not all daily resuscitation equipment checks had taken place as identified by Alliance Medical Limited.

Requires improvement



However:

- The service had enough staff with the right qualifications, skills and experience to keep people safe from avoidable harm and to provide the right care.
- Staff understood how to protect patients from abuse. Staff had level one adults and children's safeguarding training on how to recognise and report abuse, and they knew how to apply it.
- The service had suitable premises and equipment. Equipment and premises were visibly clean, and staff used control measures to prevent the spread of infection.

Are services effective?

We do not currently rate effective for diagnostic imaging services.

We found the following areas of good practice:

- Staff of different kinds worked together as a team to benefit patients. The service provided care and treatment based on national guidance and evidence of its effectiveness. Radiation protection advisers and supervisors checked to make sure staff followed guidance.
- Staff assessed and monitored patients regularly during their scan to see if they were uncomfortable or in pain.
- The service made sure staff were competent for their roles. Managers appraised staff's work performance, provided support and monitored the effectiveness of the service.
- Staff understood their roles and responsibilities under the Mental Capacity Act 2005 and in relation to informed consent.

Not sufficient evidence to rate



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

Summary of this inspection

- Two patients records showed that the patients had not signed and dated their agreement in relation to the use of their images as a teaching aid.

Are services caring?

We rated caring as **Good** because:

Good



We found the following areas of good practice:

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

Are services responsive?

We rated responsive as **Good** because:

Good



We found the following areas of good practice:

- The service planned and provided services in a way that met the needs of local people.
- The service took account of patients' individual needs and staff understanding of patients' needs ensured the service was accessible to all their patients.
- People could access the service when they needed it. Waiting times from referral to treatment and arrangements to admit, treat and discharge patients were in line with good practice.
- The service treated concerns and complaints seriously, investigated them and learned lessons from the results, and shared these with all staff.

Are services well-led?

We rated well-led as **Good** because:

Good



We found the following areas of good practice:

- Leaders had the right skills and abilities to run a service providing high-quality sustainable care.
- The service followed the Alliance Medical Limited values of collaboration, excellence, efficiency and learning.
- The service engaged well with patients, staff and the trust to plan and manage appropriate services.

Summary of this inspection

- Leaders operated effective governance processes, throughout the service and with partner organisations. The service was committed to improving services by learning from when things went well or wrong, promoting training, research and innovation
- The service improved service quality and safeguarded high standards of care through systems which identified risks, plans to eliminate or reduce risks, and were able to cope with both the expected and unexpected.
- The service collected, analysed, managed and used information well to support all its activities, using secure electronic systems with security safeguards.

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

- Not all staff know how to access information such as radiation protection meeting minutes, previous radiation protection advisor reports and the Health and Safety Executive action plan.

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	Good	Good
Overall	Requires improvement	Not rated	Good	Good	Good	Good

Diagnostic imaging

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

Are diagnostic imaging services safe?

Requires improvement 

Mandatory training

The service provided mandatory training in key skills including the highest level of life support training to all staff. However, we observed some shortfalls in staff training attendance.

During inspection we reviewed the ionising radiation training policy which was in date and due for review in August 2021. The policy outlined the mandatory training for all staff, dependent on role, who were either engaged in work with ionising radiation or directly concerned in the work with ionising radiation should be completed. For example, The essentials of positron emission tomography-computed tomography, introduction to radiation protection and radiation protection supervisor training.

Staff were introduced to and had read the positron emission tomography-computed tomography scanners local rules on induction to the service and following updates to the local rules.

The mandatory training target was 85% for Alliance Medical Limited.

Managers monitored mandatory training and alerted staff when they needed to update their training.

The mandatory training needs analysis showed the description of training, staff groups the training applied to, frequency and whether the training was online or face

to face. Mandatory training included: manual handling, conflict resolution, infection prevention and control, fire, level two safeguarding adults and children training and complaints.

Staff had completed mandatory training which included basic life support and immediate life support training sessions in 2018/19. Mandatory training statistics dated 27 December 2019 confirmed that 100% of staff had completed their training.

Staff had training on how to recognise and report abuse, and they knew how to apply it. Alliance Medical Limited (AML) provided adult and children's safeguarding training sessions at level one, two or three. Training records dated 27 December 2019 confirmed that 100% of staff had completed children's and adults level one mandatory safeguarding training sessions.

The AML safeguarding policy identified that all clinical staff should complete level two children's safeguarding training relevant to their role and attend updates every three years.

None of the four eligible staff identified to complete this training had completed it.

Staff told us that the trust had maintained responsibilities for scanning children however, the service recognised the importance of staff attendance at level three children's safeguarding training. Safeguarding training statistics provided up to 13 September 2019 confirmed that 20% which was one staff member had completed level three adults and children's safeguarding training.

Safeguarding

Diagnostic imaging

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

Identified safeguarding service leads for children and adults safeguarding were in place at Alliance Medical Limited (AML). The local safeguarding lead was the Leeds PET-CT Clinic registered manager.

The safeguarding adults and children's policies and procedures were in date and due for review in May 2021 and March 2020 respectively. The children's safeguarding policy was due to be reviewed by AML in March 2020.

The policies outlined the objectives, explained the terminology of various types of abuse, identified the duties, roles and responsibilities of staff and information sharing would be consistent with the Caldicott review (2013). Included in the policy was a standing operating procedure (SOP) on how to manage and report a safeguarding concern which complied with intercollegiate guidance (2019).

The PET-CT Centre and its team aimed to keep patients safe whilst observing the requirements as discussed in the adult and child safeguarding policy and procedure, a dual policy shared by the trust, linking with the local teams and sharing information as required.

Staff knew how to make a safeguarding referral, identify adults and children at risk of, or suffering, significant harm and worked with other agencies to protect them. Where patients images identified potential abuse suspicions staff said they would complete a safeguarding referral and follow the safeguarding procedure to report any concerns.

Managers made sure all staff had enhanced disclosure and barring service checks before they started their contracts. Three yearly reviews of enhanced disclosure and barring checks were completed.

Cleanliness, infection control and hygiene

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

Designated infection control leads were identified for the service locally and at a corporate level.

There were no incidences of a healthcare acquired infection in the last 12 full months prior to September 2019.

Staff had completed the on-line annual infection, prevention and control (IPC) module. The IPC annual report reported that all staff had completed the on-line annual IPC module.

The unit was visibly clean and had suitable furnishings which were clean and well-maintained, and staff cleaned equipment after patient contact. Daily cleaning was under a third-party agreement with the trust. The unit manager monitored performance and provided feedback on any actions.

Cleaning records demonstrated that all areas were cleaned regularly. However, we observed some gaps against the daily cleaning task sheets we reviewed dated from 12 August 2019 to 4 December 2019. Where there were gaps in checks no reasons were given as to why the checks had not taken place. An annual deep clean contract was in place; the last deep clean took place in August 2019. Occasionally additional deep cleans have been done following the scanning of an infectious patient whose scan is completed at the end of the list.

Legionella Testing completed on 10 October 2019 identified no concerns.

Staff followed infection control principles including the use of personal protective equipment (PPE). Control measures such as hand gel, aprons and gloves were available. Hand washing facilities were available, and staff had bare arms below their elbows. Two spillage kits were available and in date.

The Leeds PET-CT annual IPC audit benchmark for 2017-18 was 80%; Leeds PET-CT score was 81%. In 2018-19 the IPC benchmark was 90%; Leeds PET-CT scored 78% and in 2019-20 it was 95% for static units; Leeds PET-CT Centre scored 94%. (Source: Leeds PET-CT Centre, Annual Infection Prevention and Control Report, August 2019)

The IPC action plan was noted by the trust staff under a dual staffing agreement and ongoing actions were monitored by the registered manager and clinical lead.

Commentary in the report identified the patient referral pathway for the unit did not restrict the referral of infectious patients. Where infectious patients were

Diagnostic imaging

referred they were managed in compliance with company policy and reported via the incident reporting policy to allow trend analysis. No trends or areas of concern were identified in relation to infectious patients.

The Leeds PET-CT Centre annual infection prevention and control (IPC) report dated August 2019 confirmed that monthly infection control audits took place and outcomes were communicated to the hospital. Quarterly service reviews with the hospital included updates on cleaning and infection control audit outcomes.

The unit completed the monthly environmental monitoring tool via the SharePoint site in accordance with policy and the IPC programme during the 12-month reporting period.

Monthly staff hand hygiene audits were completed during 2019; the mean score was 98%. An area of development related to minor issues which related to bare below elbows which was addressed with staff by the unit manager.

Insertion of peripheral vascular device (PVD) monthly audits were completed for all clinical staff who undertook the insertion of PVDs. The mean score was 98% and no areas of concern noted.

Environment and equipment

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

The design of the environment followed national guidance (health building note six) and had suitable premises and equipment and looked after them well.

Scanning facilities met the required standard to comply with regulatory issues relating to health and safety, radiation protection and the environment. The facilities included:

- Five injection rooms. All injection rooms were fitted with, live only, close circuit television (CCTV), patient call bells, hand washing facilities, medical gasses and suction. We did not see a specific policy in place in relation to the use of CCTV as a means of monitoring patients.
- Laboratory / drawing-up area for the radiopharmaceuticals.

- One patient changing room.
- The toilet for use by the patient after the injection of radiopharmaceutical was called the 'hot toilet.' Designated toilets were in place because patients excreted radioactive urine post procedures. Designated toilet use reduced the radioactive risk to other patients.
- Two scanner rooms. Both rooms had piped medical gasses and hand washing facilities. CCTV and audio communications were available to the control room and a key press for keys used generally by the trust.
- Control room and reporting area.
- One store contained the network hub for Alliance Medical and a radiation protection safe that contained the hot waste during hours of operation.

The doors next to the AML office and equipment room provided the main entrance to the department. Entry was through swipe card access only and all patients were escorted.

Staff confirmed when new to the unit they had received training specific to the equipment in use in the unit, for example, the PET-CT scanner.

The service had enough suitable equipment to help them to safely care for patients.

Daily calibration check records confirmed checks had taken place for other specialist equipment in 2019, for example the glucometer.

Service records confirmed that both scanners had been serviced in 2019. The GE Discovery PET-CT 690 scanner's last quarterly service took place on the 7 December 2019. The GE Discovery PET-CT 710 scanners last quarterly service took place on the 14 September 2019; its next service is due to take place within seven days.

The GE Discovery 710 and 690 PET-CT scanners PET daily quality check records onsite confirmed daily safety checks from 3 January 2019 to 4 December 2019.

The last radiation protection advisor review took place in November 2019. To-date the report findings had not been received.

Diagnostic imaging

Local rules were present but not displayed. The local rules identified the name of the radiation protection supervisors and were dated July 2019. Staff completed the local rules sign off sheet after they read them.

If the patient wished to stop the scan they told the radiographers who then stopped the examination.

Safety signs alerted people when the PET-CT room was in use. Controlled area x-ray signs outside of the scanner rooms lit up when the room was in use. A radiation-controlled area sign and authorised persons only sign was present on the scanner doors.

All radiation room doors had signs which identified a radiation-controlled area. These included x-ray risk from radiation, risk of contamination and risk of external radiation. None of the signs had the name or contact number of the radiation protection supervisor or radiation protection adviser on.

Staff and carers used specialised personal protective equipment. Family members and/or carers stood behind a lead screen when present in the room. However, staff said this was a rare occurrence and only took place if the patient was very anxious. Staff said the trust medical physics department last maintenance test of the lead screen took place when the screen had been installed. The trust have said they are now looking into frequency of maintenance checks on the lead screens in use.

Film badges monitored staff radiation exposure. Public Health England monitored the film badges. The film badge dosimeter or film badge is a personal dosimeter used for monitoring cumulative radiation dose due to ionizing radiation. Film badges were monitored monthly and should results confirm higher than expected levels an investigation took place. The local investigation level is lower than the statutory limits identified within the local rules. Currently, three staff confirmed the use of film badge dosimeters and showed us their current film badge dosimeters.

A radio-active isotope identification device was located in the hot lab which staff used to check for the presence of radio-isotope on their hands. This device was used on each occasion a radio-isotope was used. Hands were monitored on four occasions throughout the injection preparation and disposal processes.

The department was provided with a resuscitation trolley by the trust. In addition, a paediatric resuscitation equipment bag was bought to the department by trust radiographer staff when they scanned children within the department. We asked to see the paediatric resuscitation bag whilst on site but were told it was stored away from the unit and was only present in the unit when children were being scanned.

The adult resuscitation trolley was in the unit corridor. Staff confirmed daily checks of the top of the trolley took place and checks of the whole trolley took place monthly. We saw records which confirmed resuscitation trolley checks were documented by staff when completed, however, we noted that 11 checks had been missed from August to November 2019.

The defibrillator was stored on top of the trolley was past its service date of November 2019 and the last check had taken place on the 2 December 2019. We raised this with the clinical lead and later the registered manager who said they had taken immediate action to rectify this.

Staff disposed of clinical waste safely.

Two spill kits were present in the department which were used should nuclear waste spills occur. Guidance on how to manage a spill situation was included in the local rules and radiation risk assessments.

Environmental Agency permits were in place for the accumulation and disposal of radioactive waste. In addition, permits had been obtained for open sources and sealed sources radio-isotope waste products. The last sealed source leakage tests had taken place on the 4 December 2019.

Control of substances hazardous to health (COSHH) had been completed in four areas and were dated 11 July 2019.

Assessing and responding to patient risk

Staff completed and updated risk assessments for each patient and removed or minimised risks. Staff identified and quickly acted upon patients at risk of deterioration.

The management of medical emergencies policy and procedure (v5) was due for review in March 2021. The policy identified that Alliance Medical Limited (AML) responsibilities included ensuring that the unit was

Diagnostic imaging

staffed in accordance with policy and that the minimum staffing levels supported the requirements to manage a medical emergency. A minimum of two staff one trained to immediate life support (ILS) level and one basic life support (BLS) and automated external defibrillator (AED) trained staff must be available. The policy also stated that staffing would be adjusted to reflect the dependency of patients and the service provided.

Locum, agency and bank staff prior to commencement of shift confirmed their level of training; as a minimum would be BLS with AED. Staff were advised to make sure they know where the medical emergency equipment was and familiarise themselves with local arrangements.

Staff attended six-monthly unannounced scenarios which were run by Alliance Medical Limited. These scenarios assessed the safety of the service provided to the patient by trained staff. Previously staff had attended two resuscitation simulations in May and November 2018. The May 2018 report identified no actions, whilst the November 2018 report identified three actions which had an immediate timescale applied.

Patients that required urgent onward referral were managed in compliance with policy and local procedure. Unwell patients who required transfer were cared for by staff trained to immediate life support level.

In the 12 months preceding this inspection there had been no unplanned transfers of patients to another health care provider.

Staff practice considered the AML patient identification and justification policy (for review 28 July 2020) which identified the importance of the correct identification of patients to reduce risk and increase patient safety. We saw this in action when we observed staff confirm the patients identification when the patient answered three questions specific to them.

A comprehensive radiation risk assessment had been completed in July 2019 which had resulted in some actions, some of which were confirmed by staff as being actioned. Monitoring of the progress made against these actions took place through the AML/Trust liaison meeting.

The service were supported by a medical physics expert, radiation protection advisor and waste advisor and

supervisor. We saw evidence that their advice was followed through local rules procedures, risk assessments and from minutes of joint meetings with the trust.

The hospital radiologist and radiation protection supervisor had agreed the PET- CT rooms protocols. Local rules were available.

Prior to investigations females between the ages of 18 and 55 years were asked whether they were pregnant. We saw pregnancy signs in rooms where patients stayed.

Staff who were pregnant did not enter the PET-CT scanner when it was operational. Staff said that pregnant staff had a risk assessment completed, specific dose limits were identified, and their scope of practice changed. The pregnant staff member also received an electronic personal dosimeter whose levels were audited.

Staff were not authorised to work at Leeds PET-CT without an identification badge and/or, where required, personal dosimeters.

Staff knew about and dealt with any specific risk issues.

Staff completed risk assessments for each patient on admission / arrival and updated them when necessary and used recognised tools. We observed this take place through observation of four contact telephone calls made by the administrator, again, on patients arrival to the service either by the radiographer or clinical assistant and patient risks were also documented within the three patient paper records that we reviewed.

We tracked two patients at various stages through their scanning episodes. We observed the pre— injection talk for both patients and the cannulation and injection process for one patient. We observed that staff completed checks with the patients prior to their injections and scans.

Staff shared key information to keep patients safe when handing over their care to others.

Where inpatients from the trust were scanned, effective handover of clinical care was required and documented to support continuity of care. A ward preparation guide was shared with the ward to ensure thorough preparation during the booking process. The guide was typically faxed to the ward and or emailed to a key ward contact, it was then printed and attached to the notes to ensure that

Diagnostic imaging

should the patient move ward the detail was handed over. In addition, further to examination completion and after care a ward guide was provided. Scan information was entered onto the radiology information system. When the scan required an immediate review by the doctor the scan information was highlighted to indicate this.

Radiology staffing

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

The service employed the staffing requirements to support the scanning pathway procedure to ensure that safe staffing levels were delivered. To assist in ensuring the appropriate staffing levels a staffing calculation tool was used to determine the staffing levels required for the facility based on the number of operational hours.

At the time of the inspection the service employed one registered manager, one clinical lead, two PET-CT radiographer / technician, one graduate PET CT radiographer. Two clinical assistants and an administrator.

We observed that staff were really busy on the day we inspected the service. In addition to three permanent staff one bank technician and one agency technician were working. Staff said the service did have some vacancies and as such ongoing recruitment was taking place. Current vacancies to-date included two radiographers/technicians and one graduate radiographer post. One radiographer was being interviewed next week and one technician was due to start with the centre in January 2020 once their disclosure and barring checks had been received.

Where there were short term issues that impacted on the staffing at the centre, such as sickness or holiday absence the centre was supported by the mobile fleet and measures were available within the business continuity plan.

In the last three months prior to September 2019 the service had used PET-CT technician / radiographer bank

staff on 13 occasions and PET-CT technician / radiographer agency staff on 61 occasions. The service had used 15 clinical assistants and nine administrators bank staff in the same reporting period.

The service operated shared staffing with the trust via a service level agreement (SLA) with the trust. The trust radiographers reported as part of their job plan within the SLA. Assurance of their fitness was provided to the registered manager by their line manager that they were all appropriate for their role, and that they had all had an appraisal in the last 12-months.

Trust radiographers worked on Mondays and Thursdays within the unit where they followed Alliance Medical Limited local rules, risk assessments, policies and procedures. Revalidation and appraisal processes for the trust radiographers were completed through the trust radiology services manager and staff said updates were provided at the quarterly service review meetings that the registered manager had with the trust.

Some radiographers reported outside of their trust job plans and staff said it was these staff that were granted practicing privileges. Three radiographers locally had practising privileges agreements in place with Alliance Medical Limited (AML).

The service provided an example of a blank practising privileges application form which radiographers completed as part of the application process. The application form identified a number of information requests, for example, appraisal, disclosure and barring certificate, professional registration information. Each radiographer who was on a practising privileges agreement was also issued with a contract between them and AML which they signed, dated and agreed to.

The extract of Leeds reporters provided confirmed that checks such as General Medical Council registration number and indemnity status had taken place as the relevant information was entered, for example, GMC numbers. Seven of the radiographers identified scanned on the Leeds PET-CT site.

A team of radiologists and five individuals from the administration of radioactive substances advisory committee (ARSAC's) were available to support the team as required. An ARSAC holder was available for advice at

Diagnostic imaging

all times that the centre was operational. The nuclear medicine radiologists were available during normal working hours and were the first contact, unless a specific query required ARSAC input.

Bank and agency staff received a local induction which they confirmed included mandatory training sessions. Radiographers also completed a medical device assessment for the equipment they were using.

Records

Staff kept detailed records of patients' care and treatment. Records were clear, up-to-date, stored securely and easily available to all staff providing care.

All patient care was documented in the Alliance Medical Limited (AML) electronic radiology information system (RIS) and the trust clinical record interactive system (CRIS) system.

Patient notes were comprehensive, and all staff could access them easily. We reviewed three patients paper records which were fully completed. Staff told us that these records would be scanned so they were available electronically.

Records were stored securely.

During inspection we reviewed the records management policy dated December 2016 which had a two-year review date; the policy was out of date.

When patients transferred to a new team, there were no delays in staff accessing their records.

Patients images and reports were shared with the referring hospital via the central picture archiving and communication system. Reports were emailed individually to the referring consultants secure email.

When inpatients from the trust were scanned, effective handover of clinical care was required and documented to support continuity of care. A ward preparation guide was shared with the ward to ensure thorough preparation during the booking process. The guide was faxed to the ward and or emailed to a key ward contact, it was printed and attached to the notes to ensure that should the patient move ward the detail was handed over. In addition, further to examination completion and after care the ward guide was provided

Medicines

The service used systems and processes to safely prescribe, administer, record and store medicines.

The registered manager was the designated service lead responsible for the safe and secure handling of medicines.

Medicines management was in accordance with Alliance Medical Limited (AML) policy. AML had a pharmacy advisor who supported national requirements.

Staff followed systems and processes when safely prescribing, administering, recording and storing medicines.

Staff stored and managed medicines and prescribing documents in line with the provider's policy.

Radioactive isotope storage was secured within locked cabinets which were in a locked room accessed by swipe card.

Fluorodeoxyglucose (FDG) tracer was sent to the service in a sealed container. Once the FDG had passed its quality check the keypad lock number was released to staff. Following this the FDG was assayed and rate of decay calculated on a computer to confirm patients dosage.

Controlled drugs were not stored and / or administered as part of the service provided.

All administrations of radiopharmaceutical were performed under the written authorisation of an administration of radioactive substances advisory committee (ARSAC) license holder or their delegate as appropriate. An ARSAC licence holder was available at all times when the service was operational.

Patient group directions were not used at the centre.

Radio-isotopes were only drawn up once the patient was present and calibration checks had been completed and passed.

Staff checked that they had the right patient prior to giving the radio-isotope.

Prior to giving the isotope staff told the patient what to expect and that it was important for the patient to reduce movement following the injection of the isotope.

Diagnostic imaging

Medical devices which contained sodium chloride 0.9% pre-filled syringes were used. We did not see a protocol/guidance on its use in place.

The service had systems to ensure staff knew about safety alerts and incidents, so patients received their medicines safely.

Incidents

The service managed patient safety incidents well. Staff recognised incidents and near misses and reported them appropriately. Managers investigated incidents and shared lessons learned with the whole team and the wider service. When things went wrong, staff apologised and gave patients honest information and suitable support. Managers ensured that actions from patient safety alerts were implemented and monitored.

Staff used the incident reporting system to record incidents in line with provider policy.

Root cause analysis training was available for managers and those staff who investigated incidents.

We reviewed the 'Incident Reporting' standing operating procedure (SOP) which was in date. Staff were encouraged to report incidents as they happened, and all employees worked within a fair blame culture supporting patient and staff safety.

The legal and regulatory duty of candour places a responsibility on providers of healthcare services to be open and honest with service users and other 'relevant persons' (people acting lawfully on behalf of service users) when things go wrong with care and treatment, giving them reasonable support, truthful information and a written apology. Staff we spoke with on inspection understood what duty of candour was and what their responsibilities were in relation to the duty of candour principles. Between September 2018 and September 2019, the service had not reported any incidents where duty of candour was used.

The service had reported 37 other incidents between August 2018 and July 2019; clinical seven, infection control two, information governance and security three, operational four, radiation protection 20 and radiology reporting one.

Between September 2018 and September 2019, the service had not reported any never events. Never events are patient safety incidents that are wholly preventable where guidance or safety recommendations that provide strong systemic protective barriers are available at a national level and have been implemented by healthcare providers.

The service had reported one incident of an employee's accidental overexposure to radiation in March 2019. This was reportable through Health and Safety Executive (HSE) under Regulation 26(1)(a) of the Ionising Radiations Regulations 2017(IRR17).

Alliance Medical Limited developed a learning from experience action plan following this incident. The action plan identified the 16 recommendations, the current position, action, identified lead and target completion dates which fell from June to July 2019 against each recommendation. The provider confirmed, and we saw that all these recommendations were actioned.

Staff comprehensively described the learning from the incident during the inspection.

In addition, the following actions were completed:

- A stand-alone ionising radiation training policy was produced. The policy detailed the training required and how often for all members of staff working with ionising radiation or in an environment where ionising radiation was used.
- The management of staff doses policy and procedure was reviewed to include the sharing of doses for agency staff.
- The June 2019 key points of learning risky business newsletter introduced the incident in Leeds PET-CT and said that a group of PET staff were currently looking at the options which related to guidance for long sleeves to protect arms when dispensing in PET-CT radioisotopes.
- The key points of learning risky business newsletter (August 2019) detailed the incident, learning and the subsequent actions which were put in place.

Diagnostic imaging

Learning from incidents was shared via a monthly risk bulletin and thereafter at local staff meetings. Risk Management was via a co-ordinated approach, supported by risk assessments and procedures, collated via the electronic risk management system.

Are diagnostic imaging services effective?

We currently do not rate effective for diagnostic screening services.

Evidence-based care and treatment

The service provided care and treatment based on national guidance and best practice. Managers checked to make sure staff followed guidance. Staff protected the rights of patients subject to the Mental Health Act 1983.

Staff followed up-to-date policies to plan and deliver high quality care according to best practice and national guidance.

The Medical Director was responsible for the policy, guidance and implementation of IRMER 2018 Regulations. The detailed guidance and procedures were developed by the Medical Physics advisors coordinated through the organisation Radiation Protection Committee.

The policy and procedures were available to all staff through the Alliance Medical Limited (AML) electronic information system. Hard copy versions of the documents were held at each PET-CT mobile unit or fixed site facility. Ongoing education and training programmes were administered and assured by the AML continuing professional education system (Myrus).

Leeds PET-CT had agreed a dual policy process with the trust as part of their contract which meant staff adhered to identified trust policies, protocols and procedures.

We reviewed 11 clinical policies and procedures at inspection and observed them all to be in date and evidence based.

Alliance Medical Limited Integrated governance and risk board minutes (10 April 2019) confirmed that ongoing monitoring and updating of policies and procedures, local guidelines and practice had taken place.

Scanning protocols were approved by the local administration of radioactive substances advisory committee (ARSAC). New policies and procedures were reviewed and signed by staff to confirm understanding.

The local rules for the protection of persons against ionising radiation for the service were updated in July 2019.

Alliance Medical Limited audit schedules for 2017 to 2018 confirmed audits in areas which related to the patient, quality, reporting, image quality, information governance, clinical systems and information technology. Audit frequency ranged from monthly to annual audits.

Nutrition and hydration

The service did not have facilities to provide food to patients, however, patients could access water on request.

Staff said that where patients had particular needs such as diabetes two fasting guidelines were followed. For diabetic patients who came from home they were asked to fast for four hours prior to their appointment if they were an insulin dependent diabetic and for six hours if they took tablets. This information was communicated as part of the initial contact telephone call made to the patient.

For hospital inpatients staff said the ward staff ensured that the patient was fasted for six hours prior to their scan.

Pain relief

Staff assessed and monitored patients regularly to see if they were in pain.

All inpatients were escorted from the ward and the escort stayed with the patient. Ward staff ensured that patients pain was managed appropriately before they were taken to the positron emission tomography-computed tomography scanning department.

Should a patient experience difficulties this was identified during the two-hour appointment that each patient had. The first half hour was dedicated to administration of the patient, including consent, contraindications, and any specific needs that the patient had.

Staff said they tried to ensure patients were comfortable throughout the scanning process and that patients were

Diagnostic imaging

encouraged to alert them if they were uncomfortable and needed the scan to stop. We observed that staff checked that patients were comfortable during the scanning process.

Patient outcomes

Staff monitored the effectiveness of care and treatment. They used the findings to make improvements and achieved good outcomes for patients. The service had been accredited under relevant clinical accreditation schemes.

The service did not provide a treatment to patients which enabled them to measure patient outcomes. However, the service did complete audits and quality assurance tests to ensure that they provided a service to measurable standards which they could monitor with the aim of making improvements.

The patient audits included compliments and complaints, patient satisfaction surveys and reported incidents. From the information provided and audit outcomes seen we observed good compliance and high patient satisfaction against the areas assessed

A 10% clinical reporting audit was carried out for all clinical cases; audit results were emailed to the unit manager monthly. This formed part of Alliance Medicals monthly reporting framework to NHS England on waiting times. The positron emission tomography (PET) contract activity performance for Leeds PET-CT centre from November 2018 to October 2019 ranged from 91% to 116%.

Image quality was reviewed as part of the 10% reporting audit under the national reporting framework. Additional audits had been performed on referral quality and shared with local multidisciplinary teams and referrers.

Local audits were completed to compare the key elements of the referral and scanning pathway. This included, referral to scan time and scan to report published time to make sure that the unit was providing the referrer and patient with information and scan report in support of diagnosis as soon as possible.

Staff said safety checklists were followed prior to the scan. The administration of radioactive substances advisory committee (ARSAC's) staff were available to support the team as required and when the centre was operational.

If there was an adverse finding from a scan the service asked the patient to contact their referrer, or nurse specialist as appropriate for advice and to discuss the scan results. Staff said that patients scan reports were sent back to the referring consultant and /or hospital within two days of the scan taking place so that any findings could be communicated and discussed with the patient.

The service had introduced fluciclovine as a tracer which was better as a prostate cancer imaging tool.

Competent staff

The service made sure staff were competent for their roles. Managers appraised staff's work performance and held supervision meetings with them to provide support and development.

Staff were recruited in accordance with policy. Qualifications varied dependent of area of practice and where required was verified with the relevant professional body.

New staff to the service completed a one-day corporate induction at the Alliance Medical Limited (AML) head office in Warwick.

We spoke with a staff member about their local induction. They said they had been orientated to the centres environment and had familiarised themselves with the AML policies and procedures, local risk assessments and the local rules for the PET-CT scanner. Following completion these areas were signed off on an induction sheet. We saw the completed documentation which included information about: monthly objectives, pre-PET-CT orientation, written assessment one and PET-CT orientation.

During the first two months of probation this staff member worked as a clinical assistant and their named supervisor was the clinical lead. Additional training during the six-month probation period had included cannulation training, completion of online mandatory

Diagnostic imaging

training and attendance at Immediate life support training. Set meetings with the clinical lead did not take place. Informal discussions usually took place in response to queries and questions raised.

Staff said individuals could shadow and be supported by an experienced staff member until their capabilities and skills were satisfactory.

For all agency and bank staff working at Leeds PET-CT centre the local induction process was conducted by the unit manager or a senior member of staff. The induction covered local requirements such as knowledge of the local rules document, fire evacuation plan, local staff facilities and access codes to relevant areas, introduction to local staff and training requirements where relevant.

Managers identified poor staff performance promptly and supported staff to improve.

Staff were experienced, qualified and had the right skills and knowledge to meet the needs of patients.

Managers identified any training needs their staff had and gave them the time and opportunity to develop their skills and knowledge. The service's permanent staff training needs analysis (June 2019) outlined the training required by staff role, if it was covered during induction, how frequently refresher training was required and the method the training would be delivered. A separate training needs analysis mandatory training document (dated June 2019) for bank and agency staff was also in place and contained the same information.

Staff said they had the opportunity to discuss training needs with their line manager and were supported to develop their skills and knowledge. Staff competency was achieved through competency based clinical assessments, e-learning and face to face learning in line with the training needs analysis guidance.

Audit was one tool used to monitor staff competencies, for example intravenous cannulation audits. We reviewed the findings from an intravenous cannulation internal audit conducted throughout July 2019. The findings for if the staff member had used the correct identifier in the report system which included full name and employee number showed seven out of 15 staff audited had not and six had shown inconsistencies with identifiers used. In addition, three staff had not achieved the number of cannulations to demonstrate competency.

An action plan to improve performance of the areas audited was not provided.

Managers made sure staff received specialist training for their role. The ionising radiation training policy outlined guidance on where the training could be accessed and how often it should be completed, for example spills training could be accessed locally through the radiation protection supervisor. One staff member we spoke with confirmed completion of spills training. The ionising radiation training policy also provided information on where the training should be recorded in order that evidence of compliance to external bodies could be provided.

Role specific training which related to ionising radiation (medical exposure) regulations was provided to identified staff as part of the mandatory training schedule.

Staff had received training regarding how to support people living with dementia.

All staff had received annual appraisals which comprised of individual timed objectives. New staff members had an initial appraisal after six months which was when they had completed their probation period. Currently, there were two new staff members who were due to have an appraisal completed once they had completed their probation period.

Radiographers were Health and Care Professions Council (HCPC) registered and met the standards to ensure delivery of safe and effective services to patients. The HCPC is a regulator, set up to protect the public. They keep a register of health and care professionals who meet HCPC standards for their training, professional skills, behaviour and health. From September 2018 to September 2019 all staff with professional registrations had their professional registrations checked.

Multidisciplinary working

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

The registered manager attended meetings with the trust. Close working relationships existed with the trust, hospital radiology and medical physics departments.

We saw that the team included, the centre manager, radiographers, clinical assistants, radiologists and

Diagnostic imaging

administration staff who all worked well together to provide a cohesive service to their patients. Staff had a good understanding of each other's' roles and valued each other's contribution to the team.

Staff liaised with referring professionals to ensure all necessary information was obtained prior to the patient's arrival at the department.

Referring clinicians could contact reporting clinicians to discuss results if needed.

Seven-day services

The opening hours of the centre were 7.30 am to 7.30pm Monday to Friday. Staff told us there was enough capacity by flexing shifts to open on Saturdays, dependant on referral volume pressure.

The centre operated under the national health service England (NHSE) national PET contract and sought to maintain a five-working day (TAT) which is the total testing cycle comprising of nine steps which were, ordering, collection, identification, transport, preparation, analysis, reporting, interpretation, and action. The service had a two-day result reporting window.

Consent and Mental Capacity Act

Staff supported patients to make informed decisions about their care and treatment. They followed national guidance to gain patients' consent. They knew how to support patients who lacked capacity to make their own decisions or were experiencing mental ill health. They used agreed personalised measures that limit patients' liberty.

Staff gained consent from patients for their care and treatment in line with legislation and guidance. The identification of patients reflected current guidance and consent to PET-CT scans was confirmed via the patient data form.

Staff made sure patients consented to treatment based on all the information available. We saw checks made in this area when we observed the radiographer go through information including consent prior to the radio-isotope injection being given.

Staff clearly recorded consent in the patients' records. We reviewed three patients paper records which were fully completed and contained the patients signed consent for

the scan and also for their information to be used as part of training or research. However, we observed that the patient had only ticked to confirm consent in relation to the use of their images to be used as a teaching aid for doctors.

Staff said that if a patient was unable to consent a responsible person who knew the patient could consent on behalf of the patient. Staff said checks also took place with the supervising radiologist to confirm that it was appropriate to continue with the scan.

Staff said that children and young people's consent was managed and obtained by trust staff prior to scans being undertaken.

Staff said that young person's from the age of 16 years were subject to the mental capacity act and there was a legal assumption that they were able to consent/refuse care and treatment unless there was evidence at the time that they lacked mental capacity to make that specific decision.

Staff said that a parent or clinician could not override the decision of a young person (who has capacity to make it) when they refused treatment with the consequence of death or serious deterioration. In this instance the trust would approach the courts.

Staff had completed Mental Capacity Act (2005) training as part of their safeguarding training. Training statistics confirmed 100% of staff had completed this training.

Are diagnostic imaging services caring?

Compassionate care

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

In the reporting period 1 November 2018 to 30 November 2019 5067 scans were undertaken at Leeds PET-CT; of these, 87 were private.

We reviewed the privacy, dignity and respect policy which was in date and due for review in August 2020. The policy advised staff of the importance of maintaining a patient's privacy and dignity. We observed staff maintaining

Diagnostic imaging

patients' privacy and dignity when showing the patient to their designated rooms. Staff maintained confidentiality when speaking with patients by speaking softly and closing doors.

Patients received compassionate care and were put at ease. We observed all staff were polite and courteous to patients from arriving to the time they left the department.

Staff understood the need to respect patient's personal, cultural, social and religious needs, and they took these into account.

Staff escorted patients from one area to another and treated patients with dignity and respect.

Staff confirmed with patients that they could hear the radiographer before starting the scan.

We observed staff communicating with patients through the intercom to ensure patients were as comfortable as possible during the procedure.

Staff said that patients and their families could provide feedback about their experiences through the patient satisfaction questionnaire.

Findings from the patients survey which took place from 1 August 2019 to 31 August 2019 confirmed that of the 22 patients who completed the survey all, but one patient were either satisfied or extremely satisfied with their experience. One patient identified they were neither satisfied or dissatisfied. The majority of the patient feedback described the service as 'friendly', staff were polite, very professional and informative. Some frustrations were also shared by patients despite having rated their experiences positively, for example, waiting times, cancelled appointments and what to do when waiting in the room post injection.

Patients were provided with an emailed patient survey after their scan was completed. The results were presented as percentages and comments collated for evaluation and public display in the department and were shared at quarterly service review with the trust. Each response was considered, and any actions were managed accordingly.

Family and Friends survey results were displayed in the PET-CT centre dated from 1 January 2019 to 31 July 2019. 100% of respondents said they would recommend the service to family and friends. Overall experience ratings were satisfied and very satisfied.

Emotional support

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

Patient feedback about the support they received was very positive. We spoke with three patients and one relative whose comments included 'this is the NHS at its best and they made me feel at ease.'

Staff understood the emotional and social impact that a person's care, treatment or condition had on their wellbeing and on those close to them.

We observed staff support patients in the room they were allocated and during the scanning process.

Staff said they had spent additional time with patients who were nervous about the scan procedure and anxious due to the confined space of the scanner itself.

Staff understood the potential impact a patient's care, treatment or condition had on their wellbeing and on their relatives, both emotionally and socially. Staff ensured they took time to speak to patients making sure that patient's privacy and dignity was observed.

Patients with a specific need such as dementia or learning disability were escorted, usually by a family member.

A chaperone policy was also in place which identified carers or relatives could accompany patients.

Understanding and involvement of patients and those close to them

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

Staff made sure patients and those close to them understood their care and treatment.

Diagnostic imaging

Interpreters were provided on request to allow face to face interpretation. Access to language line was also available.

Carers, or relatives could accompany patients.

Patients received information leaflets with their appointment letters. Leaflets included information about what the scan entailed and what was expected of the patient before and after the scan appointment.

Staff explained what was happening by communicating with the patient before, after and throughout the scan.

We saw staff spend time with each patient prior to their scan. During this time staff went through the patient's documentation which included the patient's medical history and safety checklist. Staff supported patients and their relatives to ask questions and confirm their understanding of the procedure they were about to have.

Patients received verbal instructions before leaving the centre in relation to post scan care.

Patients we spoke with confirmed they had been happy with their experience and were able to ask questions. They said the PET-CT scan and use of the tracer had been explained so they knew what to expect pre and post procedure.

Are diagnostic imaging services responsive?

Service delivery to meet the needs of local people

The service planned and provided care in a way that met the needs of local people and the communities served. It also worked with others in the wider system and local organisations to plan care.

The service delivered positron emission tomography (PET) scanning services to West Yorkshire via NHS England and Leeds Teaching Hospitals Trust, taking referrals for some specialist scans from as far away as Scarborough. Positron emission tomography-computed tomography, is known as PET-CT.

The service was commissioned by five clinical commissioning groups and primarily served the communities of the West Yorkshire and Vale of York regions scanning patients of all ages.

The centre operated under the NHS England National PET contract and had two PET-CT scanners on site which operated from 0730-1930 Monday to Friday. Saturday opening may also take place if referral volumes are high.

Monitoring of service delivery against the contractual agreement took place with the trust. Quarterly contract review meetings with the trust looked at progress against service delivery. Measurement of quality outcomes for example, the patient experience were also discussed.

Facilities and premises were appropriate for the services being delivered. The service operated five days per week 12 hours per day and as required on weekends. This flexibility allowed a wide range of access to appointments.

Facilities included a PET-CT control room, two scanning room and five patient rooms, two hot toilets, two hot labs, one administrator/manager office and store facilities .

The centre was accessible to users of wheelchairs and had parking spaces close to the building.

Meeting people's individual needs

The service was inclusive and took account of patients' individual needs and preferences. Staff made reasonable adjustments to help patients access services. They coordinated care with other services and providers.

Services took account of the needs of different people, for example, on the grounds of age, disability, gender, gender reassignment, pregnancy and maternity status, race, religion or belief and sexual orientation. Staff had had a good understanding of cultural, social and religious needs of the patient and demonstrated these values in their work.

Patients who required additional support due to specific needs, for example, safeguarding, sight and hearing loss the staff entered this information on the patient record. Accessibility was adequate and compliant with the 1995 Disability Discrimination Act (DDA) requirements.

Diagnostic imaging

The service was accessible to all. Reasonable adjustments enabled disabled patients to access and use services on an equal basis to others. Patients contacted the unit if they had any needs, concerns or questions about their examination prior to their appointment.

Chaperone services were available on request.

At the point of booking patients were given clear information on how to find the unit and of the parking requirements. This was also sent to all patients via email or post as required with the booking confirmation letter.

Appointments were tailored to ensure viewing of the scanner for claustrophobic patients took place prior to injection.

Patients had adequate information about their scan and when their results would be available. Patients confirmed they had time to ask any questions about their procedure. Patient feedback had not identified concerns about appointments feeling rushed.

Staff said they had ensured that appointments for new patients allowed time to ask questions.

Managers made sure staff, and patients, relatives and carers could get help from interpreters or signers when needed. Interpreters were provided on request to allow face to face interpretation; access to language line was also available.

Information leaflets could be accessed in languages spoken by patients and the local community.

Staff understood and applied the policy on meeting the information and communication needs of patients with a disability or sensory loss. Staff could access communication aids to help patients become partners in their care and treatment.

A hearing loop was available for patients and visitors with auditory impairments and was located at the trust reception.

Large font documents could be printed for visually impaired patients.

Visual guides had more photographs were provided for patients with learning difficulties such as autism to help prepare them for the visit to Leeds PET-CT.

Paediatric scanning was managed exclusively by the trust. Staff said positron emission tomography specific paediatric guides and survey feedback forms were available.

Staff had received training regarding how to support people living with dementia.

Access and flow

People could access the service when they needed it and received the right care promptly. Waiting times from referral to treatment and arrangements to admit, treat and discharge patients were in line with national standards.

In the reporting period 1 November 2018 to 30 November 2019 5067 scans were undertaken at Leeds PET-CT; of these, 87 were private.

Managers monitored waiting times and made sure patients could access services when needed and received treatment within agreed timeframes and national targets.

Referrals were received via secure nhs.net email, or via fax and was added to the trust clinical record interactive system (CRIS) system by the PET-CT liaison within the trust. The local radiologist vetted referrals according to clinical need. The administration of radioactive substances advisory committee (ARSAC) holders assigned a priority code to requests which allowed the booking team to transfer that priority into a booking list.

Appointments were scheduled with the focus being on turnaround time, for example, scan completed within five working days of referral vetting completion. Exceptions were when the referrer requested a specific window of timing for treatment or interventional consideration which may alter patient management, or patient choice.

The medical booking administrator scheduled in the next available appointment taking into consideration patient choice, for example, the patient's preference due to their diabetic status could be an afternoon appointment which allowed the patient to have a light breakfast prior to appointment.

A choice of appointments were offered to the patient by the local bookings team. A patient said they had no

Diagnostic imaging

difficulty changing their appointment and another patient said they were given a choice of times when to attend their appointment. One patient's relative said that their partner's appointment was received quickly.

Managers worked to keep the number of cancelled appointments to a minimum. In the event that an appointment has to be cancelled due to any unexpected issue the patient's appointment was rebooked as soon as possible.

The business continuity plan (v2) for Leeds PET-CT Centre identified individual responsibilities and the arrangements in place to ensure that patients received their scans at identified locations should scanning equipment break down.

From 1 September 2018 to 31 August 2019 the provider confirmed that five procedures had been cancelled for non-clinical reasons which related to machine breakdown or other equipment failure. The most frequent reason related to equipment failure. As the service could access two scanners this generally resulted in a delay for the patient rather than a cancellation.

The total number of planned examinations/procedures delayed for a non-clinical reason from 1 September 2018 to 31 August 2019 was 85. Of these 70 were due to a machine breakdown and patient transport issues also contributed.

When capacity was a challenge following a significant period of scanner down time, or tracer issues, extra days and extended lists were utilised, within the safe staffing parameters.

Managers monitored and acted to minimise missed appointments. In the event that an appointment has to be cancelled due to any unexpected issue the patient's appointment was rebooked as soon as possible.

The service operated a two day turn around scan reporting time. All patients were informed of when they could expect to receive the results from their scans, currently this was 48 hours or at the next scheduled appointment with the referring clinician.

We saw evidence the service collected data in relation to turn around times (TAT) of scan reports for both PET-CT machines the 690 and 710. We reviewed information from the 1 November 2018 to the 30 November 2019 which showed the turnaround of some of the reports

exceeded the seven-day target. For scanners 690 and 710 there were 142 (13%) reports and 458 (11.7%) reports respectively which exceeded their seven-day KPI. Turnaround times outside of the control of AML for both scanners related to six for scanner 690 and 24 for scanner 710.

Staff said to improve turnaround times additional scanning sessions were arranged on Saturdays and /or more patients were booked onto the daily scanning lists in the week.

Staff supported patients when they were referred or transferred between services.

When patients were initially contacted about their appointment they were asked if they required transport: staff said taxis were provided for patients unable to get to Leeds PET-CT centre.

Learning from complaints and concerns

It was easy for people to give feedback and raise concerns about care received. The service treated concerns and complaints seriously, investigated them and shared lessons learned with all staff. The service included patients in the investigation of their complaint.

The corporate Alliance Medical Limited 'Management of Concerns and Complaints Policy and Procedure' included a second stage process. If a response to a complaint did not meet the needs of the complainant, they could escalate their complaint to the Parliamentary Health Service Ombudsman or the Independent Healthcare Advisory Service.

The overarching aim of the policy was to ensure all staff working for the company recognised complaints played a fundamental role in the delivery of high-quality healthcare. In addition, to ensure the reasonable expectations of service users were being met and all areas of the business would use the information coming through complaints process, both informal and formal, would contribute to improvements in patient care and service delivery.

In the event that a patient has any concerns, staff on site addressed these with the patient. Where concerns were not addressed the unit, manager was informed, and the

Diagnostic imaging

patient was advised on how they could make a complaint which was supported by a patient information guide on this process. The guide was freely available throughout the department.

Where a comment or a concern has been raised with the patient advise liaison team at any of the referring hospitals, the unit manager was informed via email. An entry was made on the Alliance complaints system and were managed in accordance with the complaints policy.

From 1 September 2018 to 21 August 2019 three complaints were received which were formally investigated and upheld.

Leeds PET-CT identified five non-clinical complaints from August 2018 to April 2019. The themes of these complaints were associated with scanner breakdown, the radioactive tracer was not available, and three appointments were postponed.

The manager told us they would take feedback directly. Where a patient provided feedback, or negative concerns on the patient satisfaction surveys, the manager addressed these directly with the patient. Alternatively, if the patient left feedback anonymously, concerns were addressed to ensure improvement of service for other use

Lessons learned were shared with staff, actions agreed and implemented and shared via the bi – monthly risk bulletin.

Access to information about providing compliments, concerns and complaints feedback was available throughout the centre and also at the trust run reception desk.

Are diagnostic imaging services well-led?

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 patients and staff. They supported staff to develop their skills and take on more senior roles.

The service was managed locally by the registered manager who had responsibility for the administrative staff and clinical assistants. The unit manager reported to the head of positron emission tomography (PET) North. They also supervised the clinical lead who had responsibility for the PET-CT technicians and radiographers.

The registered manager was knowledgeable in leading the service and understood the challenges to quality and sustainability the service faced.

The regional manager supported the registered manager. The regional manager was a central contact for escalating concerns and risks to the provider-level quality and risk team and for cascading information back to the location managers.

The manager had one to one discussions with the regional manager and attended regular meetings held for all Alliance Medical Limited managers in the North region.

The clinical lead was new to the service and had been in post since June 2019.

Staff described local leadership as approachable. Staff felt that managers communicated well with them and kept them informed about any changes within the unit.

The service supported staff to develop within their roles; staff said they felt supported and gave examples how they had developed through attendance at training.

Vision and strategy

The service had a vision for what it wanted to achieve and a strategy to turn it into action, developed with all relevant stakeholders. The vision and strategy were focused on sustainability of services and aligned to local plans within the wider health economy. Leaders and staff understood and knew how to apply them and monitor progress.

Leeds PET-CT Centre statement of purpose described how the service operated.

The provider had developed a 'strategy wheel', which was a tool to show staff how the organisations values linked to the mission, vision, strategy and success.

The vision and values for the service included; Collaboration - working together and in partnership for all patients; Excellence - striving to deliver the very best to

Diagnostic imaging

ensure the highest quality of care; Efficiency - constantly seeking new ways to use resources more intelligently; and Learning – with a commitment to ensuring learning and continuously looking for improved ways of working. These values were central to all the examinations and procedures carried out daily and integrated into staff performance reviews and development.

Staff were aware and understood what the vision and values were and understood the strategy and their role in achieving it. Staff learnt about the core values at the corporate induction and through their annual performance review. All personal objectives issued at each appraisal linked to the company's objectives. An objective is a statement which describes what an individual, team or organisation is hoping to achieve.

The strategy provided a framework that promoted the compliance with best practice policies, procedures and processes in support of the identification, evaluation, treatment and monitoring of risks across all business functions within the company. Making sure that risk was reduced to an acceptable level as approved by the Executive Management team.

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.

The culture placed an emphasis on promoting patients' privacy and dignity and a desire to provide patients with a high-quality service.

The service's culture centred on the needs of individual patient groups. Staff understood the demographics of the area and the needs of the population in which they served.

Staff said they felt listened to and supported. They also could access training and development sessions to develop skills and competencies further.

Staff described an open culture with good team working and the manager and staff were proud of the team and the service they provided. We observed staff worked together within a relaxed and friendly environment. Relationships within the team were extremely positive.

Policies, procedures and guidance supported staff should they have concerns about a person's practice, for example, the whistleblowing policy.

Alliance Medical limited had appointed a 'Speak Up Guardian' to help staff if they needed to raise a concern about someone's working practice or patient safety. Alliance Medical Limited integrated governance and risk board minutes (20 September 2018) identified no concerns identified through the Freedom to Speak Up Guardians (FTSUGs). Staff felt they could raise any concerns they had with the registered manager.

Duty of candour training developed staff knowledge and understanding in this area and was included as part of their mandatory training.

Governance

Leaders operated effective governance processes, throughout the service and with partner organisations. Staff at all levels were clear about their roles and accountabilities and had regular opportunities to meet, discuss and learn from the performance of the service.

Alliance Medical Limited (AML) operated a comprehensive clinical governance framework and we saw clear governance committee structures in place.

The medical director had overall responsibility for quality and risk within AML. The AML operations structure confirmed a medical director, two directors, a consultant radiologist and a quality and risk team were in place.

The chair of the AML medicines quality committee was the medical director. A pharmacist also advised on this committee. As a sub-committee of the clinical governance committee it provided the governance and assurance regarding medicine use and supported continual quality improvement.

The radiation protection committee, a subcommittee, of the integrated governance and risk board provided assurance to the board that the governance mechanisms in place were effective.

Diagnostic imaging

The registered manager was familiar with key individuals within AML for advice and support with any issues that arose.

The registered manager had a detailed oversight of the service. The manager was able to articulate any challenges staff members were facing as well as challenges for the service. They demonstrated an awareness of the key risks to performance, quality and safety within the service.

The service had two identified governance leads; one for local issues and one for corporate issues.

The team had monthly meetings to discuss governance requirements which applied to all units. Discussions included incidents, complaints, scan reports, health and safety issues, information governance issues, and issues relevant to the service.

Discussions with staff identified they did not all know where to access specific information such as radiation protection meeting minutes, previous radiation protection advisor reports and the Health and Safety Executive action plan.

During inspection we reviewed the governance meeting minutes for November 2018 and May 2019. The meetings were held at the services' corporate headquarters. Each meeting had a set agenda, review of the previous meeting and action updates. The issues discussed were relevant to the service and supported patient safety.

Quality monitoring was the responsibility of the registered manager. Quality monitoring took place through sub committees aligned to the integrated governance and risk board. These committees included a clinical governance committee, information governance and security committee, health and safety committee, radiation protection committee, education and learning committee and research committee.

The centre manager attended service review meetings with the trust, which provided a forum to raise or discuss any issues or ideas for development.

Within AML the governance and committee structure ensured performance of the service was monitored, using five key quality indicators: Access; Quality; Turnaround of reports; Safety and Satisfaction (patients and customers).

We reviewed the operations board clinical governance report for January and February 2019. They reported upon various performance areas which were an overall corporate picture of performance across all the company's services and not site specific.

The quality and risk department within AML, regularly reviewed complaints, incidents and risks and produced a monthly newsletter entitled "Risky Business". Information within the newsletter was discussed at team meetings and circulated to staff within the service.

Infection prevention and control (IPC) activity was overseen by the infection, prevention and control committee which received specialist advice from a microbiologist and reported to the clinical governance committee. An established annual and monthly IPC programme was led by the infection prevention and control practitioner and overseen by the medical director and corporate infection prevention and control lead at AML.

There was oversight of staff training, competence and relevant staff had current professional registration. Staff were clear about their roles and understood what they were accountable for. Performance development reviews were aligned to the corporate and unit objectives. Integrated governance and risk board minutes confirmed discussion of staff compliance in completion of mandatory training subjects and other training areas.

The quality management framework's aim was to provide the principles through which the company ensured diagnostic imaging services met high standards of clinical quality and patient safety. It also outlined the duties and responsibilities of staff.

The objectives were, to ensure the provision of safe, effective and timely services, a measured, responsible outcome the services provided, continuous learning and improvement of services and the provision of an experience that met stakeholders' expectations.

The records management policy review had expired in December 2016. Following inspection, the provider submitted an updated records management policy dated 25 October 2019.

We saw evidence of a corporate audit programme with time intervals when the audits should be carried out and by who.

Diagnostic imaging

Local audits were completed to compare the key elements of the referral and scanning pathway. This included, referral to scan time and scan to report published time to make sure that the unit was providing the referrer and patient with information and scan report in support of diagnosis as soon as possible.

Image quality was reviewed as part of the 10% reporting audit under the national reporting framework. Additional audits were performed on referral quality and shared with local multidisciplinary teams and referrers.

Managing risks, issues and performance

The medical director's responsibilities included identification of clinical or quality risks to the directors and to ensure mitigation and/or management of risk took place.

The finance director's responsibilities included maintenance of the corporate risk register and was the identified senior information risk officer. The corporate risk register identified key risks at a national, regional and local level.

The integrated governance and risk board was a sub-committee of the overarching Alliance Medical Limited supervisory board established to provide assurance to the board that appropriate integrated governance and risk management mechanisms were in place and effective throughout the organisation.

Risk management was supported by risk assessments and procedures, collated via the electronic risk management system. We saw the use of risk assessments and procedures ensured risk was managed effectively as part of the patient assessment process.

The unit had local risk assessments which were subject to an annual quality assurance review (QAR), which in turn were aligned to national guidance in support of a safe and effective service. Actions from the QAR report and other audits were monitored locally and at corporate level. We saw local risk assessments which were reviewed in July and October 2019. The risk assessments identified the levels of risk for each area through a traffic light colour approach of red, amber and green. Red was the highest risk level. The risk assessments identified the scenario/activity, hazard, risk rating and further actions/controls. We observed all the relevant risks had been identified for the service through these assessments.

The service corporate risk register identified risks across the companies services. These risks were risk assessed and had a risk owner. There was evidence of actions which had been taken, what mitigation was in place and a revised risk assessment taking account of the mitigating actions. Staff told us that Leeds PET-CT did not have a local risk register in place.

The risk register was discussed at the integrated governance and risk board. Meeting minutes from both board meetings in September 2018 and April 2019 confirmed this.

We reviewed the corporate business continuity plan which was issued on the 1 August 2017. The policy was due for review in August 2019. Business continuity was defined as the capability of the organisation to continue delivery of products or services at acceptable predefined levels following a disruptive incident.

The plan was generic and ensured how the company could continue to exercise its functions in the event of an emergency. The aim was to ensure that continuity priorities and communication channels were in place to ensure an appropriate response to any disruption.

The site-specific business continuity plan was in date and due for review in June 2020. The plan identified roles and responsibilities of staff and where the alternative sites were so the service could be maintained.

A service level agreement (SLA) with the trust identified the key performance indicators and targets for Leeds PET-CT Centre. AML attended quarterly service review meetings where key performance indicators were reviewed with the local trust. Outcomes were discussed at unit meetings and vice versa as appropriate, so information was shared as necessary.

The service had indemnity insurance in place.

Managing information

The service collected reliable data and analysed it. Staff could find the data they needed, in easily accessible formats, to understand performance, make decisions and improvements. The information systems were integrated and secure. Data or notifications were consistently submitted to external organisations as required.

The medical director was the Caldicott Guardian.

Diagnostic imaging

The international organization of standardisation standard for assuring information security management systems the ISO27001:2013 - the standard for the safe and secure management of patient identifiable data had provided external assurance for information security management within this service. The department was inspected in July 2019, as part of the reaccreditation procedure for Alliance Medical Limited.

Alliance Medical Limited information technology department supported Leeds PET-CT information technology needs.

Patients images and reports were shared with the referring hospital via the primary and acute care systems (PACS) transfer from Alliance Medical Limited central PACS server. Reports were emailed individually to the referring consultants secure email.

Patients information which was shared with external parties was complied with the situation, background, assessment and recommendation (SBAR) communication tool. Staff scanned this information onto the patients electronic medical records on the radiological information system.

Quality Managers monitored business intelligence on a local and corporate level. Performance reports enabled comparisons and benchmarking against other services. Information on turnaround times, 'did not attend rates', patient engagement scores, incidents, complaints, and mandatory training levels.

Engagement

Leaders and staff actively and openly engaged with patients, staff, the public and local organisations to plan and manage services. They collaborated with partner organisations to help improve services for patients.

Weekly conference calls focused on three key goals for each manager to concentrate on within their unit. Goals focused on staff engagement, the unit and service delivery and personal wellbeing.

Patients were provided with an emailed patient survey after their scan was completed. The results were

presented as percentages and comments were collated for evaluation and public display in the department. This information was shared at quarterly service reviews with the hospital trust where the unit was based.

Family and Friends survey results were displayed in the PET-CT centre dated from 1 January 2019 to 31 July 2019. 100% of respondents said they would recommend the service to family and friends. Overall experience ratings were satisfied and very satisfied.

Findings from the patients survey which took place from 1 August 2019 to 31 August 2019 confirmed that of the 22 patients who completed the survey all, but one patient were either satisfied or extremely satisfied with their experience. One patient identified they were neither satisfied or dissatisfied. The majority of the patient feedback described the service as 'friendly, staff were polite, very professional and informative. Some frustrations were also shared by patients despite having rated their experiences positively, for example, waiting times, cancelled appointments and what to do when waiting in the room post injection.

Staff said that staff surveys were managed through an external company and actions identified at a corporate level. Local issues that required an action plan were noted as part of the staff appraisal process.

Managers made sure staff attended team meetings or had access to full notes when they could not attend. Some staff we spoke with said monthly staff meetings had taken place, the minutes of which were stored on the AML SharePoint information technology system so those staff not present could access them. We saw two examples of staff meeting minutes which took place on 25 June 2019 and 5 September 2019. Meeting minutes were also emailed to staff following the meetings.

Staff meeting minutes confirmed that staff were involved in and had received feedback about the service. On the 25 June 2019 staff had received feedback which related to the Health and Safety Executive incident. We saw that changes to practice and additional training were two areas identified. Whilst on inspection we observed staff now wore long sleeved aprons for drawing up and injecting the radio-isotopes. Other updates related to equipment, lessons from the Risky Business update and hand hygiene.

Diagnostic imaging

Bank and regular agency staff did not have access to the companies shared drive which meant they were unable to access information such as team meeting minutes and policies/procedures.

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.

Alliance Medical Limited had achieved the 'Investors in People Award', an internationally recognised standard for people management.

When patients were initially contacted about their appointment they were asked if they required transport: staff said taxis were provided for patients unable to get to Leeds PET-CT centre. The taxi contract was to improve patient transport issues.

Windows were re-introduced into the control room to improve staff work area.

A new dispensing container and hand monitoring solution were introduced within the hot laboratory.

Outstanding practice and areas for improvement

Areas for improvement

Action the provider **MUST** take to improve

- The provider must ensure that all eligible staff complete level two adult and children's safeguarding training.

Action the provider **SHOULD** take to improve

- The provider should ensure that all staff sign to say they have read any updated local rules.
- The provider should ensure that daily resuscitation equipment checks take place as identified by Alliance Medical Limited.
- The provider should ensure that all lead screens in use are maintained as per manufacturer's instructions.
- The provider should ensure that planned maintenance of the defibrillator takes place.

- The provider should develop a protocol/guidance for medical device use in respect of sodium chloride 0.9% pre-filled syringes.
- The provider should ensure that patients sign and date their agreement in relation to the use of their images as a teaching aid.
- The provider should ensure that all staff know how to access information such as radiation protection meeting minutes, previous radiation protection advisor reports and the Health and Safety Executive action plan.
- The provider should ensure that the corporate business continuity plan is reviewed as it has passed its review date of August 2019.
- The provider should ensure that they achieve report turnaround times.

This section is primarily information for the provider

Requirement notices

Action we have told the provider to take

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

Regulated activity	Regulation
Diagnostic and screening procedures	<p>Regulation 18 HSCA (RA) Regulations 2014 Staffing The provider must ensure that all eligible staff complete level two adult and children's safeguarding training. Regulation 18 (2) (a)</p>