Sheffield 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?	Good
Are services effective?	
Are services caring?	Good
Are services responsive?	Good
Are services well-led?	Good

Overall summary

Sheffield PET CT Centre is operated by Alliance Medical. The centre facilities include; reception and waiting area; an administrative area, which includes a reporting office, and a clinical area. The clinical area includes one scanner room, control room, dispensing laboratory, three uptake rooms and a changing room for patients, as well as male, female and accessible hot toilets (only to be used by patients who had their received radioactive injection).

The service provides diagnostic imaging using PET-CT equipment. A PET-CT scan is a combination of a PET (positive emissions tomography) scan and a CT (computerised tomography) scan. PET-CT scans are usually performed to help with the diagnosis, assessment and treatment of; cancer, heart and circulatory conditions and neurological (brain) abnormalities. The service can also provide CT scan only. The service carries out around 2800 scans per year.

Summary of findings

The service saw adults and children as NHS patients as well as self-funded adult patients.

We inspected this service using our comprehensive inspection methodology. We carried out an unannounced visit on 28 May 2019 and telephone interviews with patients on 5 June 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.

This was our first rating of this service. We rated it as **Good** overall.

We rated safe, caring, responsive and well-led as good. We do not rate effectiveness of diagnostic imaging services; however our findings are included in this report.

We found good practice in relation to diagnostic imaging services at this location:

- The service had enough staff with the right qualifications, skills, training and experience to keep people safe from avoidable harm and to provide the right care and treatment.
- Staff cared for patients with compassion. Feedback from patients confirmed that staff treated them well and with kindness. Patients told us all staff were helpful and understanding, informative, polite, reassuring and explained things well.
- Staff assessed and managed risks and kept clear records of patients' care and treatment.
- Staff understood how to protect patients from abuse and all staff (technologists, clinical assistants, manager) had completed level 2 training in safeguarding vulnerable adults and level 3 safeguarding children.
- The service had suitable premises and equipment and looked after them well. Equipment and premises were visibly clean, and staff used control measures to prevent the spread of infection.
- 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.
- People could access the service when they needed it. Waiting times from referral to scan were in line with good practice.
- The service planned and provided services in a way that met the needs of local people and of the individual patient.
- The service had managers with the right skills and abilities to run the service and staff described a positive culture where they were supported by their managers.
- The service improved service quality and safeguarded high standards of care through systems which identified risks, plans to eliminate or reduce risks.
- The service partnered with local organisations to plan and manage appropriate services and collaborated to deliver services effectively.

However, we also found the following issues that the service provider should improve;.

- The service provided mandatory training in key skills to all staff, however not all staff had completed formal radiation safety training appropriate to their current role.
- Managers investigated incidents and shared lessons learned with the team, although levels of harm were not clearly identified in a timely way.
- Local dose reference levels were available for PET but not CT scans.
- Local procedures did not refer to consent processes for children and young people, for example in relation to Gillick competency.
- Two-person checks were not completed where staff administer radiopharmaceuticals, in line with best practice, although this was in line with company policy.
- Staff felt leadership was not always visible at this location. Maintaining detailed management oversight of the service was sometimes a challenge.
- The service recognised there were opportunities to strengthen patient engagement.

Summary of findings

Following this inspection, we told the provider that it should make some improvements, even though a regulation had not been breached, to help the service improve. Details are at the end of the report.

Ann Ford

Deputy Chief Inspector of Hospitals (North of England)

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 safe, caring, responsive and well-led. CQC does not rate effective for diagnostic imaging services. There were areas of good practice and a small number of things the provider should do to improve. Details are at the end of the report.

Summary of findings

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Sheffield PET/CT Centre

Services we looked at
Diagnostic imaging

Summary of this inspection

Background to Sheffield PET/CT Centre

Sheffield PET CT Centre is operated by Alliance Medical.

The centre opened in November 2009. It is a private centre located on the site of Northern General Hospital in Sheffield (part of Sheffield Teaching Hospitals trust). The service primarily serves the communities of South Yorkshire and North Derbyshire but also accepts patient referrals from outside this area.

The centre provides its services under a NHS national contract arrangement.

The centre focuses on scanning of oncology patients and also takes part in some research trials. The majority of scans are PET-CT scans, although some CT only scans are also carried out.

The service is open 5 days per week (Monday to Friday) and offers around 60 slots per week between the hours of 7am and 7pm.

The centre has had a registered manager, in post since November 2017.

Our inspection team

The team that inspected the service comprised a CQC lead inspector, and a specialist advisor with expertise in radiology. The inspection team was overseen by Sarah Dronsfield, Head of Hospital Inspection.

Information about Sheffield PET/CT Centre

The centre is registered to provide the following regulated activities:

- Diagnostic and screening procedures for everyone.

The service provided diagnostic imaging services to NHS and self-funded patients.

The centre employed 7 staff (6.8 full time equivalent); one centre manager, three PET-CT technologists (including one clinical lead), and three clinical assistants.

Radiologists provided medical support and reporting of images under a service level agreement with the host trust but were not directly employed by the service.

During the inspection, we visited all areas of the centre. We spoke with five members of staff including the manager, clinical assistants and technologists. We followed a patient pathway and spoke with two patients. We reviewed information about the service including patient feedback about their experience. Following inspection, we spoke with four patients who had recently attended the centre for their scan.

There were no special reviews or investigations of the service ongoing by the CQC at any time during the 12 months before this inspection.

The service has been inspected previously, most recently in January 2014. During that inspection we found the provider was not compliant with 'Assessing and monitoring the quality of service provision'. We therefore gave them a compliance action to make sure this area was addressed. The provider responded by returning an action plan explaining how they had made changes and that they would be compliant by 14 March 2013. We inspected the service on 21 March to check the changes. The provider had a system in place to identify, assess and manage risks to the health, safety and welfare of people using the service and others.

Activity (June 2018 to May 2019)

- In the reporting period June 2018 to May 2019,
- 2878 patients attended the Sheffield PET-CT Centre;
- 2869 were NHS funded and 16 patients were self-funded, 29 were children;

Summary of this inspection

- 2869 patients attended for PET-CT scans and 7 for CT scans.

Track record on safety (June 2018 to May 2019)

- Zero Never events
- Clinical incidents: 21, of which 2 near misses, 19 unknown harm.
- Zero reportable IRMER / RR incidents
- Zero serious injuries
- Zero incidences of hospital acquired Methicillin-resistant staphylococcus aureus (MRSA),
- Zero incidences of hospital acquired Methicillin-sensitive staphylococcus aureus (MSSA)
- Zero incidences of hospital acquired Clostridium difficile (c.diff)
- Zero incidences of hospital acquired E-Coli
- Zero complaints.

Services accredited by a national body:

Alliance Medical Limited was accredited with;

- The Imaging Services Accreditation Scheme (ISAS) from July 2018 to June 2021,
- ISO 27001, the international information security standard from June 2018 to June 2021.

Services provided for the clinic under service level agreement:

The Radiation Protection Adviser, radioactive waste management, medical physics expertise, medical emergency response, reception cover and cleaning services were all provided under a service level agreement with the host trust. Specialist pharmacy support was available to the centre through Alliance Medical Limited.

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?

Good

We rated it as **Good** because:

- Staff understood how to protect patients from abuse. Staff had training on how to recognise and report abuse, and they knew how to apply it.
- The service-controlled infection risk well. Staff kept themselves, equipment and the premises clean. They used control measures to prevent the spread of infection.
- The service had suitable premises and equipment and looked after them well.
- Staff completed and updated risk assessments for each patient. They kept clear records and asked for support when necessary.
- The service had enough staff with the right qualifications, skills, training and experience to keep people safe from avoidable harm and to provide the right care.
- Staff kept detailed records of patients' care and treatment. Electronic records were clear, up-to-date and easily available to all staff providing care.
- The service followed appropriate practice when giving, recording and storing medicines.

However;

- The service provided mandatory training in key skills to all staff, however not all staff had completed safety training appropriate to their current role.
- Managers investigated incidents and shared lessons learned with the team, although levels of harm were not clearly identified in a timely way.

Are services effective?

We do not rate the effectiveness of diagnostic imaging services.

- The service provided care and treatment based on national guidance and evidence of its effectiveness. Managers checked to make sure staff followed guidance.
- Managers monitored the effectiveness of care and used the findings to improve them.
- The service made sure staff were competent for their roles. Managers appraised staff work performance with them to provide support.
- Staff worked together as a team to benefit patients.

Summary of this inspection

- Staff understood their roles and responsibilities under the Mental Health Capacity Act 2005 in relation to adults and how to support people who did not have capacity to make decisions about their care.

However;

- Local dose reference levels were available for PET but not CT scans.
- Staff were not aware of local procedures and consent processes for children and young people.

Are services caring?

Good

We rated it as **Good** because:

- Staff cared for patients with compassion. Patients told us staff were helpful and understanding, informative, polite, reassuring and explained things well.
- 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?

Good

We rated it as **Good** because:

- The service planned and provided services in a way that met the needs of local people and of the individual patient.
- People could access the service when they needed it. Waiting times from referral to scan 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?

Good

We rated it as **Good** because:

- The service had managers with the right skills and abilities to run the service and staff described a positive culture where they were supported by their managers.
- The service followed the Alliance Medical Limited values of collaboration, excellence, efficiency and learning and was committed to improving services by learning from when things went well or wrong.

Summary of this inspection

- 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 engaged with patients and staff and partnered with local organisations to plan and manage appropriate services and collaborated to deliver services effectively.

However;

- Staff felt leadership was not always visible at this location. Maintaining detailed management oversight of the service was sometimes a challenge.
- The service recognised there were opportunities to strengthen patient engagement.

Detailed findings from this inspection

Overview of ratings

Our ratings for this location are:

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

Good

Diagnostic imaging

Safe	Good
Effective	
Caring	Good
Responsive	Good
Well-led	Good

Are diagnostic imaging services safe?

Good

We rated safe as **good.**

Mandatory training

- **The service provided mandatory training in key skills to all staff, however not all staff had completed safety training appropriate to their current role.**
- There was a mandatory training needs analysis which showed the required training for staff groups, frequency and whether the training was online or face to face. Mandatory training included: manual handling, conflict resolution, complaints, infection prevention and control, fire, radiation safety, safeguarding adults and children and immediate life support training.
- Mandatory training programmes were completed using an e-learning platform and information from the service showed staff had completed 98% of mandatory training sessions overall, against a target of 90%, at the time of inspection, in May 2019. Following inspection, training compliance was confirmed as 100%. Medical staff compliance was monitored by the host NHS trust by whom they were employed, as part of the service level agreement.
- Staff were able to describe the radiation safety measures they took in their day to day work and had signed to say they had read and understood the local rules for the centre. A copy of the local rules for working with radiation were available in the control room and included specific guidance on managing any spillage and decontamination.
- We found that there was no evidence of formal completion of radiation safety training for two out of three staff in clinical assistant roles. However staff told us they had been trained by the clinical lead and worked under the supervision of a technologist at all times. This was raised with the manager during inspection who explained the clinical assistants had originally started in admistrative roles where this training was not required. The service provided evidence of completed radiation safety training promptly following inspection, as identified in Alliance Medical Ltd training needs analysis. Following inspection, we reviewed training records which also indicated clinical assistants at the centre had not completed 'Intro to PET CT' training' although this was not identified in Alliance Medical Ltd training needs analysis. However we also saw that training from the clinical lead in radiation safety was logged as completed, as part of the clinical assistant training scheme.
- Following inspection, we requested evidence of completed radiation safety training for all staff members (including e.g. cleaning operatives). This showed the registered manager had completed Radiation Protection Supervisor (RPS) training as well as a second member of staff, who was due to cover for the clinical lead while on maternity leave. The service also provided a copy of training slides on radiation awareness, a copy of which was provided to visitors to the unit, with advice on signage, controlled areas and signing in and out of the unit. This had been offered to inspectors on arrival. Following inspection, the service told us that cleaning staff had also completed this.

Safeguarding

- **Staff understood how to protect patients from abuse. Staff had training on how to recognise and report abuse, and they knew how to apply it.**
- Training records confirmed 100% staff (technologists, clinical assistants, manager) had completed level 2 training in safeguarding vulnerable adults and level 3 safeguarding children. This was good practice as intercollegiate guidance: Safeguarding Children and Young People: Roles and competencies for Health Care Staff (March 2014) states all non-clinical and clinical staff who have any contact with children, young people and/or parents/carers should be trained to level two. Medical staff compliance with safeguarding training was monitored by the host NHS trust by whom they were employed, as part of the service level agreement.
- Guidance in the form of adult and children's safeguarding policies and procedures were available which outlined staff responsibilities and involvement of other professions such as the local authority and/or police. This included guidance about female genital mutilation (FGM), modern slavery and radicalisation. Alliance Medical Ltd safeguarding policy identified all staff should also be aware of issues relation to radicalisation although specific Prevent training was not included in the the company training needs analysis.
- Staff could contact the designated safeguarding lead at the NHS host hospital for advice and support. There was a national Alliance Medical Ltd safeguarding lead. Staff we spoke with understood who to inform if they had any safeguarding concerns.
- Staff gave examples of how to protect children coming to the department, for example bringing children directly into the uptake room, to avoid the waiting area and having a parent or guardian accompany them in the scanner room if necessary. No non-patient children, for example visitors, were not allowed in the centre due to the radiation risk.
- Managers told us the Alliance Medical Ltd HR department made sure all staff had enhanced disclosure and barring service (DBS) checks before they started their contracts, and staff had now been re-checked within three years. Medical staff DBS compliance was monitored by the host NHS trust as part of the service level agreement.
- We noted that the Alliance Medical Ltd safeguarding children policy and procedure (August 2018) identified types of abuse and neglect including 'not ensuring access to appropriate medical care or treatment'. However, it did not include specific actions for staff to take in the event of a child who was not brought or who did not attend their appointment.

Cleanliness, infection control and hygiene

- **The service-controlled infection risk well.** Staff kept themselves, equipment and the premises clean. They used control measures to prevent the spread of infection.
- There was a designated infection control lead for the service.
- The unit was visibly clean and control measures such as hand gel, aprons and gloves were available. Hand washing facilities were available, and staff were seen to have bare arms below their elbows. Staff used hand gel between patients and gel was available for patient and visitor use in the main reception area and on entry to the unit.
- Sharps disposal bins (secure boxes for disposing of used needles) were located as appropriate across the service which ensured the safe disposal of sharps, for example needles. They were all clean and not overfilled. Labels were correctly completed to inform staff when the sharps disposal bin had been opened.
- Daily cleaning of the centre was carried out under the service level agreement with the host NHS trust, the unit manager checked performance and gave feedback on required actions. Staff undertook cleaning of clinical equipment according to cleaning schedules and records were logged for monitoring.
- Hand hygiene audits and audits of insertion of peripheral vascular devices were carried out monthly. The annual infection prevention and control report (Dec 2018) noted that audits had been completed for all clinical staff every month during the previous 12 months, with the mean score being 98%. There was an area of development noted for hand hygiene with minor issues relating to bare below elbows which the unit manager addressed with staff.
- We found that infection prevention and control was audited as part of the annual Alliance Medical Ltd quality assurance review and an annual report was produced. In March 2018 they achieved an overall score of 90%, meeting the 2017-18 benchmark. The unit was audited again in December 2018 achieving a high score of 95% against the 2018-19 benchmark of 90%.

- There were policies and procedures in place which provided staff with guidance on appropriate practice for example, cleaning schedules, hand hygiene and decontamination of equipment before servicing or repair. The policy also covered management of infectious patients.
- There was an appointed radiation waste advisor as part of a service level agreement with the host NHS hospital to provide waste management services.

Environment and equipment

- **The service had suitable premises and equipment and looked after them well.**
- The centre was purpose-built, it was a clean, light and airy environment split into three main areas: reception and waiting area; administrative area and a clinical area.
- Security was maintained through restricted access arrangements. There was keypad access from the waiting area into the clinical area. The clinical area had controlled and supervised areas which were clearly identified by warning signs and locked doors. There was also a warning light and entry barrier tape on the scanning room itself.
- The centre had 'cold' and 'hot 'waiting areas for patients before and after they had received their radioactive tracer injection. There was a patient changing room and individual uptake rooms for patients, where they received their injections and waited for their scan. Staff could monitor patient safety in uptake rooms and in reception, using CCTV.
- Staff could see patients from the control room during the scanning process. During scanning the patients were monitored from the control room via CCTV and staff communicated with patients via intercom throughout the scan. There was an emergency call button in the scanner for patients to use if they wanted to stop the scan for any reason.
- There was a resuscitation trolley in the clinical area outside the scanner room and daily equipment checks were completed by the technologists. Restocking of the trolley was undertaken by the host NHS hospital where the service was located through a service level agreement.
- We noted there were no paediatric defibrillator pads available on the emergency trolley. We discussed this with the manager who explained that specialist staff accompanying children attending the unit were required to bring paediatric resuscitation equipment with them and accompany the child throughout their visit – see assessing and responding to risk section.
- There was a local risk assessment which had been in place since August 2018 and was scheduled for annual review.
- All staff wore personal dose meters as per the local risk assessment, to monitor levels of radiation exposure; ring badges and waist badges were used. Eye and finger dose meters were also used and being trialled. Monthly results were monitored and action taken when results were above expected levels or to keep staff safe. For example, staff technique was observed and altered to reduce raised finger doses for a staff member working with a new type of vial. Dose meters were also provided to escorts and relatives / carers if it were necessary for them to be in the scan room.
- Specialised protective equipment was available, for example, lead aprons. These could be used by a family member or carer if they stayed in the scanner room with the patient. We requested audit information which showed the aprons had been received new to the service in December 2018. Staff told us that these should be checked annually, although the next audit date was not formally identified.
- There was a planned maintenance programme and maintenance records that showed when equipment had last been serviced and when the next service was due. All equipment checks were in date. Electrical equipment was safety tested.
- There was an agreement in place with the host NHS trust that covered checks, support and quality assurance provided by the medical physics department.
- Staff had been trained in the safe and effective use of the scanner. Technologists completed a medical devices assessment for the equipment they used to assess them as being competent.
- Staff carried out daily quality assurance checks on the scanner to ensure it performed safely and to specification. We saw records which provided evidence that daily quality assurance checks on the equipment were carried out.
- Staff told us that when there were equipment issues they contacted the medical physics department at the host NHS trust. Incident data indicated there had been

an incident where staff had not escalated to medical physics when quality assurancepoliciesan results were not as expected. The manager had discussed the learning from this with staff.
- There were fire safety signs and a fire extinguisher was accessible, fire safety checks were made weekly.
- Emergency call bells were available in the scan room and patient uptake rooms.
- Patients told us the centre was clean, calm and comfortable.

Assessing and responding to patient risk

- **Staff completed and updated risk assessments for each patient. They kept clear records and asked for support when necessary.**
- A radiation risk assessment was completed for the location.
- There were local rules for radiation safety and staff familiarised themselves with these prior to working at the centre. Safety manuals for operators and local rules were easily accessible within the scan room and were in date, although dose reference levels were not available in the scan room.
- The clinical lead and centre manager were trained radiation protection supervisors (RPS) for the service. However the manager was not aways on site and clinical lead was on maternity leave at the time of inspection. We noted that the training for the clinical lead had expired (Dec 15, 3 yearly). An alternative supervisor had been nominated while the clinical lead was on maternity leave who had also received RPS training. There were two nominated radiation protection advisers who were clinical scientists employed by the host NHS hospital.
- The most recent radiology protection advisor and medical physics expert audits of compliance with Ionising Radiation Regulations 2017 and Ionising Radiation (Medical Exposure) Regulations 2017, took place in in July 2018 and March 2019. The audits found that progress had been made in respect of the implementation of new Ionising Radiations Regulations and standards of radiation protection were in general satisfactory.
- However, the report also made several recommendations for improvements. We saw that required actions to date had been completed and progress had been made against the others. One of these was to develop a programme of contingency plan rehearsals to ensure that all staff participated in a rehearsal at least once every 3 years. A training session had taken place in April 2019. One of the recommendations due to be completed shortly after inspection was for the centre to evidence completed on-line radiation protection training for technologists and to clarify the training syllabus and required training frequency and record-keeping for this. Some of the recommendations not yet completed at the time of inspection were that the centre needed to review its policies and to maintain staff personal contamination monitoring records. The service was also recommended to begin environmental monitoring to inform the patient risk assessment.
- The 'Patient Identification and Justification of Request Policy' (v5) identified how the checking process assured staff they had the correct patient and were giving the right treatment at the right time. The three-point check was used which included checks of patient name, date of birth and address as well as any previous scans if relevant. We saw 'stop and pause' checks were completed for each patient; staff checked they had the right patient and checked against the patient documentation before entering the scan room.
- Risk assessment of the patient was via the 'PET-CT patient data form'. The patients completed this form themselves as a self-declaration which doubled as a consent form. Information included medical history and determining whether a patient could be pregnant (for females aged between 12 and 55).The technologist went through the patient data form to confirm the information the patient had provided. Completed forms were scanned onto the electronic record system.
- Staff would speak to one of the consultant radiologists if there were any concerns about the information patients had provided. Similarly, if a scan was requested which was not carried out at this location, for example a brain scan, staff would speak to the consultant. There was a radiologist on call list available and staff said they were responsive.
- If the patient was a child, there was a specific paediatric referral questionnaire for referrers which asked whether the child experienced 'needlephobia', was able to comply with the scan requirements or required pre-cannulation or a play specialist. The referral questionnaire explained that Sheffield PET CT centre had only basic resuscitation equipment for paediatric

patients and therefore children under 13 years must have the appropriate escort and resuscitation equipment brought with them in the hospital transport from the children's hospital.

- The Sheffield PET-CT paediatric process (March 2019) required that if the child was under 12 years old, the service required a specialist children's nurse and clinician with advanced paediatric life support (APLS) training accompany the child to their appointment. If the child was over 12 years old or above and the referrer indicated no escort was required, the patient could be accompanied by a parent / guardian.
- Staff confirmed this was the case; children attending the centre were generally referred from the local children's hospital. Staff pre-booked the patient with the children's hospital who provided pre-cannulation and paediatric staff, who brought appropriate emergency resuscitation equipment to escort the patient to the centre.
- In line with the up to date Sheffield PET-CT paediatric process, children who required sedation were not scanned at this unit and instead referred to other facilities so they could be supported safely.
- The booking team (clinical assistants) contacted the patient via telephone to explain the procedure and complete a safety questionnaire.
- Patients who were participating in research were booked together as a cohort, as different radiopharmaceuticals were used and protocols were agreed with the clinical research team.
- Inpatients attending the centre came with a nurse escort from the ward to ensure continuity of care and meet patient needs while they were at the centre.
- All staff were trained in immediate life support and staff were aware how to raise an alarm if a patient became seriously unwell or collapsed. The host NHS hospital provided resuscitation equipment and an emergency response team if required.
- There were alarm call bells in the toilets, uptake rooms and controlled areas and staff used CCTV to monitor patient safety in uptake rooms.
- There was an up to date standard operating procedure for staff to follow for the unwell patient and visitor. These procedures were reviewed annually and were specific to Sheffield PET CT Centre. Incident data indicated staff had acted appropriately when a patient had become unwell, although observations had not been recorded in line with the procedure.
- There had been no urgent transfers of patients from the location to another healthcare provider in the last 12 months.

Staffing

- **The service had enough staff with the right qualifications, skills, training and experience to keep people safe from avoidable harm and to provide the right care.**
- The unit staffing was planned in line with the Alliance Medical Ltd policy which stated that at least two members of staff on duty must be trained in the recognition and management of the deteriorating patient. In addition, a clinical member of staff trained in immediate life support must always be on site during service delivery.
- We found that the minimum staffing for the PET-CT service was three members of staff, with at least one trained technologist, one ILS trained clinical assistant and one administrator (minimum of two ILS trained staff members). If this model were used, the number of patients would be reduced, to ensure the service remained safe.
- The usual staffing was two trained technologists, one clinical assistant and two administrators, depending on the expected activity. The reception area was staffed by a clinical assistant between 7am and 7pm.
- The centre employed seven staff (6.8 full time equivalent); one centre manager, three PET-CT technologists (including one clinical lead), and three clinical assistants / administrators.
- Radiologists provided medical support and reporting of images under a service level agreement with the host trust but were not directly employed by the service.
- One member of staff had joined and one had left the service in the last 12 months (clinical assistant/admin assistant). There were no staff vacancies at the time of inspection.
- The service did not use agency or bank staff in the three months before the inspection. The centre used its own staff or staff from other Alliance Medical mobile units could be deployed in the event of staff sickness, to maintain minimum staffing levels. Staff from other units received an induction prior to working on the site.
- Staff sickness rates for the last three months before inspection were not provided by the service. The manager reported low levels and was supported by the Alliance Medical Ltd HR department as required.

- There was a rota in place for consultant radiologist reporting of scans and radiologist support was available in person or via the telephone from the host NHS hospital. If a radiologist was not available, then the emergency medical team was called where necessary.
- If a patient required pre-cannulation (for example for children), this would be arranged by the referring clinical team as there was no medical support for cannulation at the centre.
- When a child required a PET-CT scan, the children's hospital provided pre-cannulation and paediatric staff and emergency resuscitation equipment to accompany the patient to the centre, in line with the Sheffield PET-CT paediatric process.

Records

- **Staff kept detailed records of patients' care and treatment.** Electronic records were clear, up-to-date and easily available to all staff providing care.
- Patient and clinical information was recorded on an electronic radiology information system.
- The service had agreed arrangements to enable electronic referrals and reporting information to be shared between the host NHS trust and Alliance Medical Limited systems. An image exchange portal and a direct virtual private network (VPN) were used to share the relevant data such as report and images relating to the PET-CT scan.
- Information sharing between Alliance Medical and other organisations adhered to agreed protocols/guidance. The Alliance Medical Limited 'Image transfer and case management team' managed IT processes and security centrally.
- The centre used paper records for some patient requests, for consent and the patient safety checklist. Once the patient had completed the safety checklist and consent document, these were scanned in at the end of the day, so the records were held electronically.
- We reviewed five patient records; the electronic records system identified patient details, the request and confirmation, who scanned the patient, the dose and amount of radiopharmaceutical given, and whether the patient had a cannula. Details of the scan protocols used, scan area and positioning were recorded on the patient data form.
- All staff had completed information governance and data protection training and records .
- Records were kept in line with the principles of the Data Protection Act 1988.

Medicines

- **The service followed appropriate practice when giving, recording and storing medicines.**
- The service followed safe practice when giving, recording and storing medicines. There was a named pharmacist for Alliance Medical Ltd who staff could contact for advice if required. The registered manager was the service lead for the safe and secure handling of medicines.
- The centre and the radiologists they worked with, all held current licences with the Administration of Radioactive Substances Advisory Committee (ARSAC) which meant they were legally able to use nuclear medicines. There were three ARSAC licence holders and two delegates.
- Radioactive pharmaceutical agents were prepared at an external facility and delivered to the centre. As they could degenerate quite quickly, stocks were ordered on a named patient basis, were delivered daily and staff worked to run scans on time wherever possible. Medicines were stored securely within a designated room, in line with the manufacturers' recommendations, to ensure they would be fit for use.
- A radioactive medicine, FDG (fluorodeoxyglucose) was given to patients intravenously as a tracer for the PET-CT scan. The scan uses a small amount of the medicine to show differences between healthy tissue and diseased tissue.
- FDG injection details including type of cannula used, whether extravasation (leaking from the vein) occurred and any normal saline used for flushing were recorded on the PET-CT patient data form and the information was input to the radiology information system at the end of the procedure.
- If a patient needed to take any other medicines while they were in the department this was also recorded on this form.
- The radio-active tracer was administered by trained technologists using patient specific directions. A patient specific direction is a written instruction, from a qualified and registered prescriber for a medicine including the dose, route and frequency, or appliance to be supplied or administered to a named patient after the prescriber has assessed the patient on an individual basis.

- The patient specific directions were checked with the radio-active tracer to ensure this was the correct dose and in date before being administered by the technologist. The administration details, including batch number, were recorded on the patient's PET-CT patient data form which was signed by the technologist who administered the tracer. These details were also entered onto the radiology information system record. Managers said a second check was not completed as only one tracer was usually used at the centre. A different tracer was used in research trials and these occasional appointments were batched together. Following inspection, managers told us staff worked in line with Alliance Medical Ltd policy which did not require second checking. Although it would be best practice to use a second check to verify correct dose as well as correct tracer, it was noted that guidance from the Royal Pharmacological Society no longer required a second check, as it was found that double-checking did not reduce error.
- If a patient was late for an appointment the staff considered the life expectancy of the FDG and whether there would be an impact on other patients if a scan started late. Staff told us these considerations sometimes meant that patients who were late needed to have their appointment rearranged.
- Emergency medicines including an anaphylaxis kit, were stored securely and monthly checks were made to ensure these were within expiry dates (anaphylaxis is a severe potentially life threatening allergic reaction).
- Patients were advised in the information leaflet to take their own medicines as usual on the day of their scan.
- No controlled drugs or contrast were used as part of this service.
- Staff including clinical assistants, completed training in medicines management as part of mandatory training.

Incidents

- **Managers investigated incidents and shared lessons learned with the team, although levels of harm were not clearly identified in a timely way.**
- There was an incident reporting and investigation policy in place which included duty of candour policy. The duty of candour is a statutory (legal) duty to be open and honest with patients (or 'service users'), or their families, when something goes wrong that appears to have caused or could lead to significant harm in the future.
- Staff could articulate what duty of candour meant and understood the principles of being open with patients when something went wrong, although incident data did not indicate any examples.
- Staff told us they could report incidents and were encouraged to do so, using an electronic reporting system. Staff told us radiation incidents would be reported to the CQC as appropriate under Ionising Radiation (Medical Exposure) Regulations; any relevant incidents would be reported to the Health and Safety Executive in line with regulatory requirements and organisational policy.
- Learning from incidents across the Alliance Medical Limited group was shared via a monthly risk bulletin and we saw that incidents were discussed with staff at their meetings.
- Staff told us the quality and risk team reviewed reported incidents monthly to ensure all incidents, near misses and accidents were accurately reported with appropriate actions taken.
- There had been no never events or serious incidents at the Sheffield PET-CT centre in the reporting period between January 2018 and December 2018. There were no Ionising Radiation (Medical Exposure) Regulations incidents for the same time period.
- From June 2018 to May 2019 the service had reported 2 near misses and 19 incidents, with unknown harm. The service completed around 2800 scans per year.
- These incidents included; discrepancies in the referral and vetting information received (6), patient anxiety, claustrophobia or unwell (4), data protection / admin error (3), lost staff radiation monitoring ring (2), cannulation failure or extravasion (2). Other incidents included, discrepancies from clinical audit identified (2)– one missed information not passed on; scanner values outside of QA (1), unable to log on to IT system (1).
- Incident records we reviewed identified actions taken but did not clearly show how incidents were categorised regarding degree of harm or potential harm to staff or patients.
- We were not assured that all incidents were always appropriately reported or categorised. In one recorded incident, a patient received the wrong scan as the wrong radiopharmaceutical was specified in the vetting process (PSMA and not FDG). We saw that there was learning from this incident as a subsequent near miss was identified and averted. However, the Alliance

Medical incident reporting procedure (2018) highlights that incidents involving 'Administration of the wrong radioactive isotope' must be escalated and reported as an incident which may require reporting externally. For example, this type of incident would require reporting to CCQ under the Ionising Radiation (Medical Exposure) Regulations 2017 (IRMER). However, information from the provider indicated no IRMER reportable incidents from January to December 2018. New national guidance on externally-reportable incidents was introduced in June 2019; Significant Accidental and Unintended Exposures under IRMER Guidance for Employers and Duty Holders (SAUE).

- In another example, staff described a spillage incident due to poor continence care and a near miss where a letter with patient details had been found mis-filed among other papers., but these incidents were not logged in the incident records we reviewed This meant the service may have missed opportunities to learn from some incidents.
- We reviewed records which showed some incidents appeared to have been under investigation for some time. For example, nine incidents reported between January and March 2019 were marked as 'under investigation' or 'awaiting final approval' at the time of inspection. Following inspection, the service told us actions and preventative measures had already been taken for those 'awaiting final approval' and three of the remaining incidents were under active investigation.

Are diagnostic imaging services effective?

We do not rate the effectiveness of diagnostic imaging services; however, we found the following during our inspection.

Evidence-based care and treatment

- **The service provided care and treatment based on national guidance and evidence of its effectiveness. Managers checked to make sure staff followed guidance.**
- The service provided care and treatment based on national guidance and evidence-based practice, which included the Administration of Radioactive Substances Advisory Committee and Ionising Radiation (Medical Exposure) Regulations.
- The provider had developed local rules for PET-CT scanning, these were comprehensive and in line with practice guidance. The local rules were based on the relevant Medicines and Healthcare products Regulatory Agency guidelines. PET-CT guidance was based on Royal College of Radiology guidelines.
- Staff could access local and Alliance Medical Ltd policies and procedures online as required. Policies we reviewed were in date, with identified review dates.
- Local rules and protocols for routine scan sequences and referral specific scans were up to date and readily available in the scan room . The protocols were developed by the trust radiologists and included paediatric dose reference levels.
- However, while local dose reference levels (DRLs) were available for PET, they were not for CT, where national DRLs were used. DRLs were not displayed in the scan room. We raised this with the manager who explained dose reference levels were established locally by following Alliance Medical Ltd corporate policy. The manager told us that a CT audit was in progress which had indicated the dose could be reduced and that work to resolve this was in process. Managers told us PET DRLs were audited annually and had been audited in the last 6 months. However, they had identified that the CT dose reference levels had not been audited.
- There was a local up to date PET-CT paediatric process in place, which booking staff followed, although during inspection, clinical staff told us they were not aware of a standard operating procedure for scanning children.
- Local audits compared the key elements of the referral and scanning pathway. This included referral to scan time. The audit also included scan to report published time. Although, the service provided a scan only provision it audited 'scan to report published' times to ensure the unit provided the referrer and patient with information and scan report in support of diagnosis as soon as possible. Scan image quality was reviewed by radiologists. The service had local key performance indicators (KPI's) agreed with commissioners at the point of contract agreement.
- Staff attended service review meetings with the host NHS hospital where KPI's were reviewed and outcomes discussed at unit meetings as appropriate.

Nutrition and hydration

- Patients could access water while waiting for their scan and were offered a hot or cold drink and a biscuit following their scan. A sandwich or hot meal could be arranged on request; for example if a patient was waiting a long time for hospital transport.
- The patient information leaflet explained the need for fasting and that staff would contact patients a few days before to check if they were diabetic or had any other needs.

Pain

- Staff completed training in moving and positioning people and were aware patients could experience discomfort during scans. Positioning aids were available if needed and staff checked on patients' comfort via the intercom during the scan sequences.

Patient outcomes

- **Managers monitored the effectiveness of care and used the findings to improve them.**
- Performance was monitored monthly, within the organisation, with a focus on areas such as incidents, training compliance, patient satisfaction and complaints.
- The centre had a key performance indicator of completing 100% of scans within seven days of referral. Between June 2018 and May 2019 we saw that 84% of patients had received a scan within five days of referral and 94% within seven days.
- Local audits were completed in line with Alliance Medical Limited audit schedule for 2018 and 2019. This included audits relating to quality, reporting, image quality, information governance, clinical systems and information technology.
- Reporting of scans was completed by radiologists employed by the host NHS trust. Reporting was audited by the Alliance Medical Ltd case management team monthly and any discrepancies were highlighted and communicated back to reporters.
- The most recent radiology protection advisor and medical physics expert reports, in July 2018 and March 2019 found standards of radiation protection were in general satisfactory and included a number of recommendations, for which the service had developed an action plan.
- There was a quality assurance mechanism in place which included the audit of image quality. Results from the audit of 307 images from January 2018 to December 2018 showed that 97.39% of images from this centre had an image quality score of five. Image quality was rated on a scale of one to five with one meaning the images were uninterpretable and five meaning the images were perfect / had no artefacts. None of the images were graded as one or two, one was graded as three (one or more sequences may have artefacts – with considerable impact on the diagnostic value of the images) and seven were graded as four (minor artefact no impact on diagnostic value). These results were better than the cumulative Alliance Medical Limited data which showed 64.07% achieving a score of five.
- The service through Alliance Medical Limited was accredited with the Imaging Services Accreditation Scheme from July 2018 to June 2021.

Competent staff

- **The service made sure staff were competent for their roles.** Managers appraised staff work performance with them to provide support.
- Staff (including any bank staff from other units) completed an induction and completed clinical skills matrix documentation when new to the service. The induction included familiarisation with policies and procedures, which included local rules specific to the centre and scanning equipment used.
- Staff competencies were checked via individual cannulation audits quarterly. The areas assessed included: number of cannulations, number of success attempts and unsuccessful attempts. Records showed all staff tested were competent to perform cannulation.
- Information provided by the service showed all staff had received their annual appraisal and six monthly reviews as appropriate, for 2018/19. Appraisals included a review of the clinical skills matrix to determine training needs and/or confidence in completion of specific skills and setting of objectives.
- Staff told us they were occasionally offered opportunities to attended specific courses with Alliance Medical Ltd or online, relevant to their continuing professional development, although time for this was not formally allocated.
- Staff could discuss any significant events with the manager or at team meetings, although they did not describe a formal system of clinical supervision.

Good

Diagnostic imaging

- Staff explained that the duties of the clinical lead had been temporarily shared among the team until planned maternity cover started. There were also designated staff leads for resuscitation and infection control.
- The professional registration status of the registered manager (radiographer) had been checked and had been revalidated within the last 12 months. There is no professional registration scheme for technologists; managers checked their qualifications, skills and experience.
- Managers explained all staff complete AML e-learning and there was also an Alliance Medical Limited clinical assistants training scheme.

Multidisciplinary working

- **Staff worked together as a team to benefit patients.**
- Technologists and clinical / booking assistants supported each other to provide good care. Staff told us there was effective external team working and a good atmosphere at work, where people worked together to meet demand.
- Radiologists at the host NHS trust were contactable for support and undertook vetting and reporting for the service. The centre was also supported by staff from the host NHS trust for medical physics support, cleaning and waste disposal.
- Managers met regularly with the NHS host trust to review service performance and this was fed back via staff meetings at the unit.
- Staff working in the service undertook scans for local NHS providers and worked with a variety of referrers to increase the number of e-referrals.

Seven-day services

- The service was not open seven days. However, appointments were offered from 7am to 7pm Monday to Friday. Staff worked flexibly to offer additional appointments on Saturdays, for example to ensure sufficient capacity around bank holidays.

Health promotion

- The centre provided a scanning service only that included routine questions in the patient data form and the well-being checks during the appointment.
- Health promotion information was not displayed in clinical or waiting areas.

Consent and Mental Capacity Act

- **Staff understood their roles and responsibilities under the Mental Health Capacity Act 2005 in relation to adults and how to support people who did not have capacity to make decisions about their care.**
- All staff received training regarding mental capacity and consent as part of their safeguarding adults training. Staff were aware of their responsibilities in relation to best interests, deprivation of liberty and FGM. Staff we spoke with understood mental capacity and informed consent and patients were given enough information to consent to the PET-CT scan.
- If a patient lacked capacity, staff told us they would refer back to the radiologist and consider decisions in the best interests of the patient. There was a consent policy available for staff to support this.
- There was a process in place which combined patient consent with other recorded information; a 'PET-CT patient data form' form was given to patients to complete as a self-declaration of medical history and which doubled as a consent form. This ensured patients were informed of the risks of PET-CT and were checked to ensure there were no contraindications for the scan going ahead.
- We observed staff obtaining verbal consent from patients before providing care or treatment.
- There was a local paediatric process however this did not specifically refer to issues of consent, for example Gillick competency. Gillick competency principles help people who work with children to balance the need to listen to children's wishes with the responsibility to keep them safe. Staff told us children 12 years and under were always accompanied by a specialist children's nurse for their scan appointment.

Are diagnostic imaging services caring?

Good

We rated it as **good.**

Compassionate care

- **Staff cared for patients with compassion.** Patients told us staff were helpful and understanding, informative, polite, reassuring and explained things well.

- Feedback from two patients we spoke with on the day and four patients we spoke with following inspection, was positive. Patients confirmed that staff introduced themselves, put them at their ease, were friendly and treated them with kindness.
- We observed professional and caring interactions between staff and patients, both during their time in the department and during phone calls. Staff were patient-focussed and considerate.
- Staff maintained confidentiality when speaking with patients on the phone by making and receiving appointment calls in the office, away from the public waiting area
- Patients were shown to individual uptake rooms to maintain privacy and dignity. Patients could use a private changing room if required. Patients would rest in uptake rooms while waiting for their scan. Staff could monitor patient safety in uptake rooms using CCTV. Staff used the Alliance Medical Ltd policy on using CCTV, which included seeking verbal consent during the patient safety questionnaire discussion and using posters to advise patients and visitors that CCTV was in operation.
- Staff ensured patients' personal belongings were placed in individual lockers when the patient went into the scan room.
- Staff escorted patients from one area to another and treated patients with dignity and respect.
- Results from the Sheffield PET CT Centre patient survey from January to December 2018 showed that 118 of the 119 patients who responded were satisfied or very satisfied with the care and treatment they received and 93% would recommend the service to family or friends.
- One suggestion from the patient survey was to have gowns available to further help maintain dignity. Another suggestion from the survey was to have a blanket available as patients could be cold lying still for long scans. The service told us gowns and blankets were available on patient request.

Emotional support

- **Staff provided emotional support to patients to minimise their distress.**
- Patient feedback was that staff were reassuring had helped them to feel calmer about the procedure. One patient said staff also offered to help with filling in forms.
- Staff told us that patients could visit the unit prior to their appointment if they were worried about coping with the procedure and that children could be offered a visit to prepare. Children were accompanied by a specialist children's nurse for support and older children would usually come to the unit with a parent or guardian. If a scan could not go ahead because a patient was distressed, staff would report this as an incident.
- Staff told us how they supported patients within the scan room for example when patients may be nervous about the scan procedure or anxious due to the confined space of the scanner itself. They explained that a relative or carer or interpreter could stay in the room with the patient if necessary and gave examples of when they had done this, with patients who were extremely anxious or claustrophobic. The local rules allowed for this and safety protection equipment was available.
- Patients we spoke with had received information from staff about what to do following their scan and how to limit any radiation dose to others.

Understanding and involvement of patients and those close to them

- **Staff involved patients and those close to them in decisions about their care and treatment.**
- Staff sent patients an information leaflet, explaining the procedure, before their appointment.
- The patients we spoke with said they were given enough information before the scan so they and their relatives would know what to expect. One patient we spoke with said it would be helpful to clarify that it is the waiting time following injection and not the injection itself which takes a long period, as they felt this was not clear in the patient leaflet. One patient said staff encouraged them to ask as many questions as they liked.
- Staff spent time with each patient prior to their scan and went through medical history, safety questions and contraindications with patients to ensure they understood what was to happen and that they were aware of any risks to safety. Patients were encouraged to ask questions and confirm their understanding of the procedure they were about to have.
- Patients told us staff let them know when their results would be available and to expect to receive the results from their referring clinician. The patients we spoke with following inspection had not had the opportunity to give their feedback to the service using the patient

survey as they did not use email. Managers said that this had been identified as an area for further development and new paper patient feedback leaflets had been ordered.

Are diagnostic imaging services responsive?

Good

We rated it as **good.**

Service delivery to meet the needs of local people

- **The service planned and provided services in a way that met the needs of local people.**
- The centre was located on the ground floor, accessible for wheelchair users and there were parking spaces next to the building. A hearing loop was available. There was a designated patient waiting area with appropriate seating, space for wheelchair users and an accessible toilet for patients.
- The uptake rooms had prints of tranquil local landscapes on the walls, which had been installed following a patient suggestion.
- Patient appointments were usually provided Monday to Friday. Staff worked flexibly to offer additional appointments on Saturdays, for example to ensure sufficient capacity around bank holidays.
- Since January 2018 staff had changed their working hours, moving from scanning 15 patients per day to 17 per day between 7am and 7pm. Staff told us this meant better turnaround time and also offered greater choice to the patient in regards to appointment times.

Meeting people's individual needs

- **The service took account of patient's individual needs.**
- There was an induction hearing loop available for patients with reduced hearing range and a wheelchair and patient trolley were available to help staff support patients with mobility issues.
- Staff booked professional interpreter services as required at the point of appointment booking. However we did not see information leaflets in other languages available at the centre to reflect the demographic of the local population.
- Referrers were asked to provide information about any additional needs the patient may have to ensure the service could respond to them. The patient information leaflet also explained the service would ask about any specific adjustments or care needs and help them to access the service, for example to match appointment times to fit with travel time.
- Posters advised patients that a chaperone service was available.
- We did not see evidence of any specific policy or staff training in supporting people with complex needs, for example a learning disability or mental health concerns. Technologists had received training in how to support people living with dementia although clinical assistants had not.
- Staff gave examples of making adjustments to support patients with disabilities, for example allocating longer appointment times and offering practical support with completing forms or moving safely around the unit. However the service did not fully meet the NHS Accessible Information Standard (AIS). The AIS requires services to identify, record, flag, share and meet the information and communication needs of patients, relatives and carers with a disability, impairment or sensory loss.
- For safety reasons whilst a friend, relative or carer could accompany patients to the hospital, they were not routinely able to go with them into the preparation or scanning areas. However, exceptions were made where necessary for example for a parent to accompany a child, where an interpreter was needed or if a patient was extremely distressed.
- Patients were reassured that a member of the team would be watching the scan from the control room and if they had any concerns during the procedure they could communicate with them via a two-way microphone.
- Staff gave patients clear information on how to find the unit and the parking arrangements, during the booking process. There was parking available on the NHS host trust site, with disabled parking near the centre.
- Hot beverages, water and snacks were provided in the waiting area for patients following their appointment, as patients were required to fast for several hours prior to their scan.
- One suggestion in the patient satisfaction survey was that it would be helpful to be able to listen to music

when they were in the scanner to distract them from the noise and enclosed space. There was a CD player / radio in the scan room which was available on patient request.

Access and flow

- **People could access the service when they needed it.** Waiting times from referral to scan were in line with good practice.
- Referrals were initially received via the e-referral system or via a paper request and were entered on the radiology information system. Staff then assigned a request to an Administration of Radioactive Substances Advisory Committee (ARSAC) certified radiologist or delegate (technologist) for vetting and triage.
- Once triaged, the local bookings team (administrators/ clinical assistants) reviewed the referrals for any specific requirements then contacted the patient via telephone to explain the procedure, complete a safety questionnaire and make the booking, within 5 days of triage. If there was a need for a patient to be scanned the same day or within 1 day, this would be discussed with one of the ARSAC holders.
- Managers monitored waiting times and made sure patients could access services when needed and received treatment within agreed timeframes and national targets. The manager told us that where capacity issues arose, consideration was given to running additional appointments on a Saturday, subject to safe staffing or alternatively referring to another Alliance Medical Ltd location to ensure a timely response.
- During the period June 2018 and May 2019, 2,878 patients were scanned in the service. Of these 2,869 were NHS patients and 9 were private patients for PET-CT scans and 29 were children. The service saw 7 private patients for CT scans during the same period. On average, the service scanned 60 patients per week, 240 per month.
- From June 2018 to May 2019, 84% of referrals were received via the e-referral system and the service was working with referrers to increase engagement towards a target of 95%.
- Patients who required urgent cancer appointments were scanned within two weeks of referral as all referrals were usually scanned within 5 days.
- Patients we spoke with told us that the service was easy to access, staff were efficient, they had been given clear information when staff telephoned them to arrange their appointment and they had not experienced any delays.
- Staff told us patients were seen on time and it was rare for patients to have to wait more than a few minutes past their appointment time. This was particularly important as the nuclear medicines given to enable the scan images degenerated very quickly.
- Staff told us that most patients were given a 30-minute time slot and that this was usually enough time. Some scans were expected to take longer and 45 or 60 minute appointment slots were arranged when necessary.
- From June 2018 to May 2019 the average time from referral to scan was under two working days. The longest wait was four days in November 2018 and three days in December and January 2019, which was due to supply problems with the radio-active tracer. Staff told us that patient choice was the most frequent reason for patients waiting longer.
- From June 2018 to May 2019 the time taken to report the results after a scan, was one day. This was consistent across the 12 month period.
- During this time 84% of patients were scanned within five working days and 94% within seven days. The longest turnaround time was in November 2018 when 59% of patients were scanned within five working days and 82% within seven days.
- From June 2018 to May 2019 the centre reported that 296 appointments had been cancelled and rebooked, the majority due to an issue with the supply of the radioactive tracer in autumn 2018. The manager told us that there had been a problem over a period of a few weeks that had led to appointments being unable to go ahead and had resulted in a backlog. Opening times had been extended to 10pm to address this and patients had been rebooked when appointments could not go ahead.
- However, we noted that some patients had been cancelled and re-booked more than once during this time. We noted that the clinical decision-making process for prioritising and re-booking cancelled patients was carried out by a technologist and managers were informed after two cancellations. This

could mean managers or radiologists may not have oversight of potential delays which could impact patients' onward treatment pathway. We fed this back to the manager following inspection.

- We reviewed incident data and noted that this type of delay or re-booking was not reported as an incident. With regard to delays, there had been one reported incident where a patient was rebooked for the following day following unsuccessful cannulation. There had been one reported incident where a patient felt unwell in reception whilst waiting for a delayed PET scan after 7 hours of fasting (March 19). There had been one reported incident where a patient's onward care pathway had been delayed by one week due to previous imaging having been requested but not supplied to the reporter in time.
- Managers told us the main supply issue and the backlog of appointments was now resolved. There were no current capacity or waiting list issues.

Learning from complaints and concerns

- **The service treated concerns and complaints seriously, investigated them and learned lessons from the results, and shared these with all staff.**
- There was a corporate Alliance Medical Limited 'management of concerns and complaints policy and procedure' which included a second stage process. If a response to a complaint did not meet the needs of the complainant then they could escalate their complaint to the Parliamentary Health Service Ombudsman or the Independent Healthcare Advisory Service.
- Leaflets were displayed in the reception area which gave information on how to raise concerns or complaints. The patient information leaflet also outlined how to contact the customer care team via email or by telephone to make a complaint.
- Staff told us people could raise concerns through emailing the customer care team directly or by using patient satisfaction surveys which were emailed to patients after their appointment.
- The patients we spoke with were satisfied with their care at the centre but had not received the opportunity to comment on the service as they did not use email. The manager told us they were looking into other ways to gather patient feedback.
- Staff told us they had changed the décor in the uptake rooms in response to patient feedback that it was a boring place to wait.
- The centre had not received any formal complaints from June 2018 to May 2019.
- All staff had completed a mandatory training module on the management of complaints and conflict resolution.
- Staff told us they had never had any formal complaints but that there had been some difficult conversations with patients when appointments had been cancelled due to FDG failure. Staff explained that if patients had been cancelled twice, this was reported to the manager and that the service could offer patients assistance with transport.
- Staff told us if a patient raised any issues or difficulties with them they would deal with their concern at once or report to the manager.
- Lessons learned from complaints across the Alliance Medical Limited group were shared with staff via the monthly bulletin which is sent to all staff and discussed at team meetings. We found that complaints from across the Alliance Medical Limited group were analysed for themes and lessons for improvement. A trend analysis of complaints across the business areas helped identify similar areas of concern that were addressed at corporate and local level through the monthly quality and risk report. The monthly quality and risk report included an overview of complaints trends discussed at board level
- The 'concerns and complaints' procedure identified the complaints process and how Alliance Medical Limited complied with 'duty of candour' by sharing information with patients, their families/carers or nominated other. Staff understood the principles of being open and gave examples of keeping patients informed when things went wrong for example cancellations due to FDG failure or where a scan could not go ahead due to a vetting issue or discrepancy.

Are diagnostic imaging services well-led?

Good

We rated it as **good.**

Leadership

- **The manager of the service had the right skills and abilities to run a service providing high-quality sustainable care. However staff felt leadership was not always visible at this location.**

- The service was led by the centre manager who was the registered manager for the service. The registered manager had responsibility for the day-to-day running of the centre and two other locations. An experienced member of staff was designated as clinical lead for any immediate queries from technologists. The registered manager also worked occasional clinical CT scanning shifts at this site, to maintain clinical competency and skills by working as part of the team.
- Staff said they felt that leaders were approachable, although, not always visible. They told us this was because the registered manager (RM) managed two additional locations and was generally onsite less than two days a week. The RM was contactable by phone when not on site although staff would usually approach the clinical lead with any immediate queries. However as this lead was currently on materity leave, her duties had been shared among other staff until a maternity cover post began. The RM recognised this was a challenge and also expressed confidence in the experienced staff team to act within their scope.
- The registered manager was supported by a regional operations manager who 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 regular contact and with the regional manager and attended regular meetings held for all Alliance Medical Limited managers in the North region.

Vision and strategy

- **The service had a corporate vision for what it wanted to achieve.**
- The vision and values for the service had been developed for the Alliance Medical Limited group and included; Collaboration - working together and in partnership for all patients; Excellence - striving to deliver the very best to 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.
- The aim of the service was to provide high standards of diagnostic imaging to meet the needs of referrers and their patients and to aims to provide flexible booking arrangements to make sure that examinations can be carried out as soon as possible at a time convenient to the patient. Staff we spoke with understood the priorities for the service.
- Staff followed the corporate strategy which was aligned with staff performance development reviews and service delivery against the business plan was discussed at team meetings.
- The centre generally used the annual internal quality assurance review process to identify areas for service development, as part of Alliance Medical Ltd's national PET CT contract. Although there was no formal local strategy for the unit, the manager described some future plans for the PET-CT centre, for example further increasing electronic referrals and increasing patient engagement.

Culture

- **There was a positive culture and a sense of common purpose based on shared values.**
- There was a culture where there was an emphasis on compassionate care and a desire to provide patients with a high-quality service.
- Staff described a culture with good team working, with colleagues described as approachable and flexible.
- The service promoted a culture of openness and honesty. Staff felt able to escalate concerns and issues to managers within the service.
- Staff commented that managing cancelled appointments due to FDG failure had been a challenge and had an impact on morale.
- Alliance Medical limited had a whistleblowing policy for staff to refer to and had appointed a 'speak up guardian' to help staff if they needed to raise a concern about someone's working practice or patient safety. Staff felt they could raise any concerns they had with the centre manager or the Alliance Medical Limited management team.
- The manager and staff were proud of the team and the service they provided.

Governance

- **The service systematically improved service quality and safeguarded high standards of care by creating an environment for excellent clinical care to flourish.**

- 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 who regularly reviewed complaints, incidents and risks and produced a monthly newsletter, which was reviewed at local team meetings.
- The radiation protection committee, a subcommittee of the IGRB provided assurance to the board that the governance mechanisms in place were effective.
- The registered manager at Sheffield PET-CT centre was responsible for local quality monitoring and complied with the corporate governance framework. The manager was able to articulate challenges and risks to the service. They demonstrated an awareness of the key risks to performance, quality and safety within the service. Maintaining detailed oversight of the service was sometimes a challenge given the limited time spent on site at Sheffield, while also responsible for two additional locations.
- The centre manager attended quarterly service review meetings with the NHS host trust to review the service level agreement, service performance and any issues relating to referrals and reporting. This was fed back via staff meetings as appropriate.
- There were monthly team meetings to discuss governance requirements which apply to all units, which include incidents, complaints, scan reporting times, health and safety and issues from the monthly bulletin. Issues relevant to the service were discussed and actioned. Local service delivery against the business plan was reviewed.

Managing risks, issues and performance

- **The service had systems in place to identify risks, plan to eliminate or reduce them, and cope with both the expected and unexpected.**
- In addition to the Alliance Medical Limited risk register, the service kept and updated a local risk register which included a risk assessment, mitigations to reduce risks and review dates.
- There was a specific radiation risk assessment which was updated annually and the service had advice and support from a radiation protection adviser, a radioactive waste adviser and a medical physics expert to manage risks to the service.
- The service had updated the fire risk assessment within the last 12 months and had identified an action plan according to this advice.
- There were a number of actions identified from the last radiation protection report and medical physics report – see assessing and responding to risk section, above.
- The service received an annual internal annual quality assurance review (QAR) which was aligned to national guidance. Actions from the QAR report and other audits were monitored locally and at corporate level.
- There was a business continuity plan in place which included planning for power outage and IT system failures. The plan had been tested in staff scenario training in March 2019. Back-up generator power was provided by the NHS host hospital.

Managing information

- **The service collected, analysed, managed and used information well to support all its activities, using secure electronic systems with security safeguards.**
- The service through Alliance Medical Limited was accredited as compliant with ISO27001 in June 2018, until June 2021. This is the international standard for assuring Information Security Management Systems; the standard for the safe and secure management of patient identifiable data. This means systems, policies and procedures had been reviewed by an external registered auditor. Information governance training was provided for staff.
- There were systems and processes in place to maintain security of information including patient records and where information was transferred between the service and the host NHS trust and other referrers, for example for referrals and reports. The service had worked with NHS partners to establish an electronic referral system and to overcome technical issues. This had increased the number of e-referrals to 80% against a target of 95% (April 2019) and the service was working with referrers to continue to reduce the number of paper-based referrals.
- Information was collected and analysed to monitor and improve performance.

Engagement

Good

Diagnostic imaging

- **The service engaged with patients, staff, the public and local organisations to plan and manage appropriate services and collaborated with partner organisations effectively.**
- The service used an email survey to gather views and suggestions from patients following their appointment, which had been completed by 199 patients from January to December 2018.
- Feedback from the patient survey had improved the service, for example, patients had commented about the environment feeling 'depressing' as there was little or no decoration on the walls. As a result, vinyl wallpaper with photographic local views has been installed in the scan room, in each uptake room, and in the corridor area. Magazines were available for patients and visitors to read while waiting.
- However, patients we spoke with told us they did not use email and had not had an opportunity to give their views. The manager told us they wanted to further develop the opportunities for patient feedback and had ordered paper leaflets to address this.
- The service held monthly staff meetings to discuss issues such as incidents, complaints, scan reports, health and safety issues, delivery against business plan, information governance, what went well and what didn't go so well and to review service delivery against the business plan. Staff meeting minutes were produced and emailed to staff. A quarterly brief from the UK managing director for Alliance Medical Ltd was also shared with the team which included an invitation for all staff to provide feedback.
- Annual staff surveys had taken place to capture staff views. The service did not provide the outcomes and action plans associated with the last staff survey.

Learning, continuous improvement and innovation

- **The service was committed to improving services by promoting training, research and innovation.**
- The service had worked with NHS partners to establish an electronic referral system and to overcome technical issues. They were the first service within Alliance Medical Ltd to use this e-referral system for all patients. Managers told us this meant staff could book patients in more quickly than most other centres within the group.
- The centre was involved in supporting research trials into nuclear medicine treatments and molecular imaging

Outstanding practice and areas for improvement

Areas for improvement

Action the provider SHOULD take to improve

- The provider should ensure all staff working at the centre complete radiation safety training appropriate to their current role and in line with legislation.
- The provider should ensure that dose reference levels are identified and available both for CT and PET scans.
- The provider should consider auditing company policy not to use second person checks, when staff administered radiopharmaceuticals. The provider should ensure all incidents are recorded, categorise levels of harm effectively and investigate incidents in a timely way.
- The provider should ensure that clinical staff who work with children have appropriate knowledge of local procedures and consent processes for children and young people, for example in relation to Gillick competency.
- The provider should consider extending training in learning disability and dementia to clinical assistants and ensure staff are aware of issues relating to radicalisation.
- The provider should consider whether management resourcing provides sufficient detailed oversight of the centre.
- The provider should continue to develop further opportunities for patient engagement and feedback which all patients can access.
- The provider should consider how to fully meet the requirements of the NHS Accessible Information Standard (AIS) to support patients, relatives and carers with a disability, impairment or sensory loss.