

Cobalt Health

Quality Report

Cheltenham Imaging Centre,
Linton House Clinic,
Thirlestaine Road,
Cheltenham,
Gloucestershire.
GL53 7AS

Tel: 01242 535910

Website: <https://www.cobalthhealth.co.uk>

Date of inspection visit: 9, 10 and 17 July 2019

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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?

Are services caring?

Good



Are services responsive?

Outstanding



Are services well-led?

Good



Summary of findings

Letter from the Chief Inspector of Hospitals

Cobalt Health is operated by Cobalt Health and provides services to patients across Gloucester, Hereford and Worcester. The Cobalt Imaging Centre in Cheltenham opened in 2006. The centre provides Positron emission tomography-computed tomography (PET/CT) (a nuclear medicine technique), Computed Tomography (CT), Cone Beam Computed Tomography (Cone beam computed tomography is a medical imaging technique consisting of X-ray computed tomography where the X-rays are divergent, forming a cone), 3.0T Magnetic Resonance Imaging (MRI) (medical imaging technique used in radiology to form pictures of the anatomy and the physiological processes of the body), high field open MRI, ultrasound and digital radiography. The service also provides a fleet of six mobile MRI scanners and one mobile CT scanner which are located in various regions across the UK. Cobalt Health also provides consultation rooms for orthopaedic surgeons to facilitate a one-stop service for outpatients, with diagnostic imaging carried out during the consultation.

The service provides diagnostic imaging services for children under the age of 18 years of age and adults.

We visited the clinical imaging centre in Cheltenham and six mobile units. Cobalt Health also provides a satellite service at The Institute of Translational Medicine Imaging Centre at the Queen Elizabeth Hospital (QEH) in Birmingham. This is a satellite MRI facility supporting a wide range of research and clinical service for the QEH. However, this location was not inspected during this inspection as it was recently inspected in January 2019 and rated good.

We inspected this service using our comprehensive inspection methodology. We carried out the announced part of the inspection on 9, 10 and 17 July 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 it as **Good** overall.

- The service provided mandatory training in key skills. Staff understood how to protect patients from abuse and the service worked well with other agencies to do so
- The risk of infection was managed well. Staff used equipment and control measures to protect patients, themselves and others from infection. They kept equipment and the premises visibly clean. The design, maintenance and use of facilities and premises kept people safe.
- Staff completed and updated risk assessments for each patient and removed or minimised risks.
- There were sufficient numbers of staff with the necessary skills, experience and qualifications to meet patients' needs. The service made sure staff were competent for their roles. Managers appraised staff's work performance.
- The service managed patient safety incidents well. Staff recognised and reported incidents and near misses. Managers investigated incidents and shared lessons learned with the whole team and the wider service.
- The service provided care and treatment based on national guidance and evidence-based practice. Managers checked to make sure staff followed guidance.
- Staff monitored the effectiveness of care and treatment in line with contractual arrangements with commissioners. The service had been accredited under relevant clinical accreditation schemes.
- Staff treated patients with compassion and kindness, respected their privacy and dignity, provided emotional support to patients, and supported and involved patients, families and carers to understand their condition and make decisions about their care and treatment.

Summary of findings

- The service planned and provided care in a way that was tailored to the needs of local people and the communities served. It also worked with others in the wider system and local organisations to plan care. 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 exceeding national standards.
- Leaders had the integrity, skills and abilities to run the service. They understood and managed the priorities and issues the service faced. They supported staff to develop their skills and take on more senior roles.
- Staff felt respected, supported and valued. They were focused on the needs of patients receiving care.
- 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.

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

- Patient group directions used by the service did not have the required authorisation as recommended by national guidance.
- Risk assessments were not always documented to provide an audit trail behind the rationale for the decision.
- Daily cleaning records were not maintained to demonstrate cleaning had taken place.
- There was limited documentation regarding additional patient care carried out by the service.
- Further work around audit was required as there was not always a formal process to identify the actions required to make the necessary improvements where audits had not met required targets.
- There were limited risks associated with children attending the service on the risk register.
- We were not assured that risks were being regularly reviewed and discussed and that mitigating actions were being acted on. It was unclear whether actions associated with risk mitigation had been completed and implemented.
- Meeting minutes did not always identify the depth and detail behind discussions held.
- There was no evidence to demonstrate that recommendations from the staff survey had been acted on or implemented.

We also found areas of outstanding practice:

- Staff worked closely with the referring NHS trust to carry out additional scans when significant findings were identified. This prevented patients from having to return to the service for additional scans which could lead to a delay in accessing treatment.
- The provider offered 800 free scans to support the local NHS trust to meet demand and ensure timely diagnostic scans for patients.
- Cobalt Health provided facilities free of charge for the local NHS trust to carry out 'one stop' clinic for patients referred for musculoskeletal complaints. Patients could receive scans and advice or treatment without the need for further waiting to attend for scans.
- Cobalt Health provided facilities free of charge to accommodate a breast screening service provided by the local NHS trust to help them meet demand.
- Following this inspection, we told the provider that it must take some actions to comply with the regulations and that it should make other improvements, even though a regulation had not been breached, to help the service improve. We also issued the provider with two requirement notices. Details are at the end of the report.

Nigel Acheson

Deputy Chief Inspector of Hospitals (South Region)

Overall summary

Cobalt Health is operated by Cobalt Health and provides services to patients across Gloucester, Hereford and

Worcester. The Cobalt Imaging Centre in Cheltenham opened in 2006. The centre provides Positron emission

Summary of findings

tomography-computed tomography (PET/CT) (a nuclear medicine technique), Computed Tomography (CT), Cone Beam Computed Tomography (Cone beam computed tomography is a medical imaging technique consisting of X-ray computed tomography where the X-rays are divergent, forming a cone), 3.0T Magnetic Resonance Imaging (MRI) (medical imaging technique used in radiology to form pictures of the anatomy and the physiological processes of the body), high field open MRI, ultrasound and digital radiography. The service also provides a fleet of six mobile MRI scanners and one mobile CT scanner which are located in various regions across the UK. Cobalt Health also provides consultation rooms for orthopaedic surgeons to facilitate a one-stop service for outpatients, with diagnostic imaging carried out during the consultation.

The service provides diagnostic imaging services for patients over the age of 18.

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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

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- Staff completed and updated risk assessments for each patient and removed or minimised risks.
- There were sufficient numbers of staff with the necessary skills, experience and qualifications to meet patients' needs. The service made sure staff were competent for their roles. Managers appraised staff's work performance.
- The service managed patient safety incidents well. Staff recognised and reported incidents and near misses. Managers investigated incidents and shared lessons learned with the whole team and the wider service.
- The service provided care and treatment based on national guidance and evidence-based practice. Managers checked to make sure staff followed guidance.
- Staff monitored the effectiveness of care and treatment in line with contractual arrangements with commissioners. The service had been accredited under relevant clinical accreditation schemes.
- Staff treated patients with compassion and kindness, respected their privacy and dignity, provided emotional support to patients, and supported and involved patients, families and carers to understand their condition and make decisions about their care and treatment.
- 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. 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 exceeding national standards.
- Leaders had the integrity, skills and abilities to run the service. They understood and managed the priorities and issues the service faced. They supported staff to develop their skills and take on more senior roles.

Summary of findings

- Staff felt respected, supported and valued. They were focused on the needs of patients receiving care.
- 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.

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

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- Risk assessments were not always documented to provide an audit trail behind the rationale for the decision.
- Daily cleaning records were not maintained to demonstrate cleaning had taken place.
- There was limited documentation regarding additional patient care carried out by the service.
- Further work around audit was required as there was not always a formal process to identify the actions required to make the necessary improvements where audits had not met required targets.
- There were limited risks associated with children attending the service on the risk register.
- We were not assured that risks were being regularly reviewed and discussed and that mitigating actions were being acted on. It was unclear whether actions associated with risk mitigation had been completed and implemented.

- Meeting minutes did not always identify the depth and detail behind discussions held.
- There was no evidence to demonstrate that recommendations from the staff survey had been acted on or implemented.

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Summary of findings

Our judgements about each of the main services

Service

Diagnostic imaging

Rating

Good



Summary of each main service

The service provided diagnostic and imaging services through the provision of a number of diagnostic imaging modalities for both NHS and private patients.

We rated this service as good because caring and well led were good. Responsive was outstanding, however safe required improvement.

Summary of findings

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Good 

Cobalt Health

Services we looked at

Diagnostic imaging

Summary of this inspection

Background to Cobalt Health

Cobalt Health is operated by Cobalt Health. The Cobalt Imaging Centre opened in Cheltenham in 2006. The service also has a fleet of mobile units which are located in different regions around the UK.

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

Cobalt Health is registered to provide the regulated activity:

- Diagnostic and screening procedures
- Treatment of disease, disorder and injury

Our inspection team

The team that inspected the service comprised a CQC lead inspector, one other CQC inspector, and a specialist advisor with expertise in diagnostic imaging. The inspection team was overseen by Mary Cridge, Head of Hospital Inspections.

Information about Cobalt Health

Cobalt Health provides diagnostic imaging services at its imaging centre in Cheltenham providing services across Gloucestershire, Hereford and Worcestershire. The service also has a fleet of mobile units, including six MRI scanners and one CT scanner which are located across different regions in the UK. The service is commissioned through a local NHS hospital trust, NHS specialised commissioning, a local Clinical Commissioning Group and the NHS Supply Chain Framework Agreement. The service also has a service level agreement with a London mental health trust to provide open scanning for claustrophobic patients. Just over 60% of the work carried out by Cobalt Health across all modalities was for NHS patients. The remaining 40% was carried out on privately funded patients or funded via research.

During the inspection, we visited the imaging centre in Cheltenham and six the mobile units. We spoke with 28 staff including radiographers, administration staff, and senior managers. We spoke with eight patients and one relative.

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 once previously in 2013. The inspection found the service was meeting all standards of quality and safety it was inspected against.

Activity (June 2018 to June 2019)

- 10,727 patients were seen at the imaging centre for MRI. Of these patients, 162 patients were under 18 years of age which equated to 1.5% of the number of patients who had attended the centre for MRI over the year.
- 3,105 patients were seen in PET/CT at the imaging centre. Of these, five patients were under 18 years of age. This equated to 0.2% of the patients seen across the year.
- It is estimated that about 39,000 scans were carried out on the mobile units between this time period. The number is not definitive because Cobalt do not keep a record of activity when the mobile unit is booked by an NHS trust as the data is held on their computer systems. This data belongs to the trust and is reported on nationally.

Track record on safety between April 2018 and April 2019:

- 0 Never events

Summary of this inspection

- 0 serious incidents
- 31 Complaints

Services accredited by a national body:

- Quality Standard for Imaging (QSI) (October 2018) formally Imaging Services Accreditation Scheme (ISAS)
- ISO 9001:2015 quality management standard (October 2018)

Summary of this inspection

The five questions we ask about services and what we found

We always ask the following five questions of services.

Are services safe?

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

We found the following issues that the service provider needs to improve:

- Patient Group Direction (PGDs) were in use without the required authorisation to enable their use.
- Daily cleaning records were not maintained to demonstrate cleaning had taken place.
- Individual risk assessments for people attending the service were not always documented, therefore there was no record of the rationale behind decisions made and actions taken.
- There was limited documentation regarding additional patient care carried out by the service.

However, we found the following areas of good practice:

- Staff received effective mandatory training in the safety systems, processes and practices.
- There were systems, processes and practices essential to keep patients safe from abuse, and staff understood their responsibilities to report safeguarding incidents.
- Infection risks were controlled.
- The design, maintenance and use of facilities prevented patients from avoidable harm.
- Comprehensive risk assessments were carried out for patients using the service.
- There were sufficient numbers of staff with the necessary skills, experience and qualifications to meet patients' needs.
- Arrangements for managing radioactive medicines protected patients from avoidable harm.
- There was an effective system in place for reporting incidents. Staff understood their responsibilities to raise concerns, to record safety incidents, concerns and near misses.

Requires improvement



Are services effective?

We do not currently rate effective for diagnostic services due to insufficient data being available to rate these services' effectiveness nationally.

We found the following areas of good practice:

- Relevant and current evidence-based guidance, standards, best practice and legislation were used to identify and develop how services and care were delivered.

Summary of this inspection

- Patients had access to food and drink at the imaging centre in Cheltenham.
- The effectiveness of care and treatment was in line with contractual arrangements with commissioners.
- Staff had the right qualifications, skills, knowledge and experience to do their job.
- Staff worked as a team to benefit patients.
- Staff understood the relevant consent and decision-making requirements of legislation and guidance, including the Mental Capacity Act 2005.

Are services caring?

We rated it as **Good** because:

We found the following areas of good practice:

- Patients were treated with kindness, dignity and respect. This was reflected in feedback we received from patients and from the way staff interacted with patients.
- Patients received information in a way they understood and felt involved in their care. Patients were always given the opportunity to ask staff questions, and patients felt comfortable doing so.
- Staff were aware of the needs of patients attending the service and how scan-related anxiety could impact on patients receiving their diagnosis and a treatment delay. Staff were supportive of anxious or distressed patients.

Good



Are services responsive?

We rated it as **Outstanding** because:

We found the following areas of good practice:

- The service planned and provided care in a way which was tailored to meet the needs of local people and the communities served.
- The involvement of other organisations and the local community was integral to how services were planned. The service worked with local partners to increase their capacity to improve patient experience and support system-wide working.
- Patients individual needs were central to the planning and delivery of tailored services. Patients could access services easily, appointments were flexible and waiting times short.
- The services provided reflected the individual needs of the population served and ensured flexibility, choice and continuity of care.

Outstanding



Summary of this inspection

- The service was performing highly with waiting times from referral to treatment and data demonstrated the service exceeding national standards.
- Staff worked closely with the referring NHS trust to carry out additional scans when significant findings were identified. This prevented patients from having to return to the service for additional scans which could lead to a delay in accessing treatment.
- The provider offered 800 free scans to support the local NHS trust to meet demand and ensure timely diagnostic scans for patients.
- Cobalt Health provided facilities free of charge for the local NHS trust to carry out 'one stop' clinic for patients referred for musculoskeletal complaints. Patients could receive scans and advice or treatment without the need for further waiting to attend for scans.
- Cobalt Health provided facilities free of charge to accommodate a breast screening service provided by the local NHS trust to help them meet demand.
- Patients we spoke with told us they knew how to make a complaint or raise concerns about the service. Complaints were responded to in a timely way.

Are services well-led?

We rated it as **Good** because:

We found the following areas of good practice:

- Leaders had the skills, knowledge, experience and integrity to manage the service and understood the challenges to providing high quality sustainable care.
- There was a clear vision with quality and safety as the top priorities.
- Staff felt respected, supported and valued and were focused on the needs of patients receiving care.
- Electronic patient records were kept secure to prevent unauthorised access to data.
- The service gathered patients' views and experiences

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

- Not all staff were clear about the values of the service.
- There was not always a formal process to identify the actions required to make the necessary improvements where audits had not met required targets.
- Meeting minutes did not always provide detail around the discussions held.

Good



Summary of this inspection

- It was unclear whether actions associated with risk mitigation had been completed and implemented and we were not assured risks were regularly reviewed and discussed.
- There was no evidence to demonstrate that recommendations from the staff survey had been acted on or implemented.





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	 Outstanding	Good	Good
Overall	Requires improvement	N/A	Good	 Outstanding	Good	Good

Diagnostic imaging

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

Are diagnostic imaging services safe?

Requires improvement 

Safe means the services protect you from abuse and avoidable harm.

We rated safe as **requires improvement**.

Mandatory training

- **The service provided mandatory training in key skills.** Staff completed mandatory training in safety systems, processes and practices. Mandatory training was completed in a number of subject areas including, but not limited to, basic life support, immediate life support, equality and diversity training, consent, mental capacity and information governance. In addition, staff received training on radiation risks where this was pertinent to their role.
- Mandatory training records for staff were held electronically by the central team and each member of staff also had access to the mandatory training record. The training matrix identified when each staff member had completed and were due to refresh their mandatory training. The service did not keep records of compliance with mandatory training for radiologists working under practicing privileges. Documentation stated radiologists were up-to-date with their mandatory training and regular updates at the time of the appraisal but did not include the date training was completed.
- Mandatory training was completed mostly electronically via e-learning. There was also one face-to-face day which staff had to attend on a yearly basis. The agenda for this day was adapted each year according to the training needs of the staff. Mandatory training was

reviewed over a fixed year period. For the year from January to December 2018 there was 86% compliance with face-to-face mandatory training against a 100% target. E-learning training records showed the large majority of the 87 staff had completed their e-learning training. Only four staff were out of date with equality and diversity training, three with health, safety and welfare and two with patient consent training. Staff spoke positively of the content and quality of the mandatory training available to them.

- The service had come to an agreement with staff to ensure e-learning training was completed in a timely way. Due to the demand for the service, staff did not usually have time in their working day to complete training. Recognising this, the senior team now allowed staff to complete mandatory training at home and paid staff to do this. This ensured staff remained compliant with mandatory training.
- There were processes to ensure relevant safety checks were carried out when agency staff were called in to fill rota gaps. The service checked references and qualifications, professional registration, enhanced disclosure and barring service (DBS), original identification documentation and mandatory training certification.

Safeguarding

- **Staff understood how to protect patients from abuse and the service worked well with other agencies to do so. Staff had training on how to recognise and report abuse, and they knew how to apply it.** There were systems and processes reflecting relevant safeguarding legislation to safeguard adults. The service had a protection of vulnerable adults' policy and safeguarding children policy available for staff. The policy outlined the responsibilities of the staff in

Diagnostic imaging

reporting concerns and how to do this. The policy also contained contact details for the local authority in Gloucestershire and the action which should be taken by staff operating in the mobile units when they had safeguarding concerns about a patient.

- There was a system to ensure there were always staff members on duty with the correct level of safeguarding training. Most staff were up-to-date with their regular safeguarding training. Two members of staff needed to refresh their safeguarding children level one and two training. Three members of staff were due training to refresh safeguarding adults' level one, and two members of staff were due safeguarding adults' level two training. Only one member of staff was out of date with level one training but was in date with their level two safeguarding training. Seven members of staff had also received training in safeguarding level three and were all in date with this training. This met intercollegiate guidance 'Safeguarding Children and Young People: Roles and competencies for Health Care Staff' (January 2019) and would enable staff to recognise any safeguarding concerns.
- Staff understood their responsibilities to report safeguarding incidents. Staff were able to tell us the action they would take if they had safeguarding concerns in accordance with the service's safeguarding policies and procedures. For example, if non-accidental injuries were detected during scans or on reporting the scan results.
- Processes to ensure the right patient received the right scan were embedded. We observed staff pause and check with patients identify, the correct procedure they were attending for and the anatomical part they were expecting to be scanned. This formed part of standard processes to ensure the right scans were carried out for all patients and risks were assessed to safeguard patients.

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. However, the service did not maintain records to demonstrate daily cleaning had been carried out.** Standards of cleanliness and hygiene were maintained. The unit in Cheltenham and the mobile units looked visibly clean. There was an infection control

lead for the service and there had been no healthcare acquired infections one year prior to our inspection. The service had infection prevention and control (IPC) policies and procedures

- Precautions were taken when patients were due to come to the service with suspected communicable diseases. Patients were scheduled for appointments at the end of the day, when a deep clean of the area could be completed.
- The service met National Institute for Health and Care Excellence (NICE) QS61 statement three (2014): People receive healthcare from healthcare workers who decontaminated their hands immediately before and after every episode of direct contact or care. We observed staff consistently adhering to the World Health Organisation: five moments for hand hygiene when providing diagnostic screening.
- Staff followed national guidance (NICE) QS61 statement five (2014) for the insertion of cannulas (thin tube inserted into the vein) for administration of contrast, to minimise the risk of blood stream infection. Staff washed their hands and used aseptic techniques as set out in the guidance. Once the diagnostic scan had been completed, staff removed the cannula promptly.
- There were no daily checklists or cleaning records to demonstrate that equipment was cleaned daily. We observed staff clean scanning equipment between each scan with antibacterial wipes. The deep cleaning audit for the imaging centre identified that discussions were ongoing about providing radiographers with protected time to clean the unit at the end of the working day. At the time of our inspection we did not know the outcome from these discussions.
- Deep cleaning records for the imaging centre in Cheltenham showed 100% compliance with deep cleaning between January to March 2019 and 98% compliance between April to June 2019.

Environment and equipment

- **The design, maintenance and use of facilities and premises kept people safe. The building housing the diagnostic suites were purpose built and met safety requirements. However, staff did not have access to paediatric resuscitation equipment in case of an emergency.**

Diagnostic imaging

- Equipment was serviced and maintained in line with manufacturers' guidance. Records showed that servicing and maintenance was up to date for all equipment located at the imaging centre and on the mobile units.
- Equipment on the mobile units was mostly checked daily to ensure safety. A test referred to as 'the water bottle test', was carried out in the MRI scanner to ensure to ensure they were in working order, along with checks of other equipment vital to ensure the smooth running of the day. This included the resuscitation equipment, oxygen, lift and telephone lines. Weekly tests were also carried out as required by the manufacturers of the scanning equipment, where the results were reviewed by the manufacturers to enable the early identification of faults. These tests also occurred at the imaging centre. However, we were not always able to find comprehensive records that these tests had been completed.
- The arrangements for managing waste and clinical specimens kept people safe. There were facilities to separate waste into clinical and non-clinical waste. Waste from the PET/CT suite was monitored before being disposed of securely and the service held the correct license to remove this waste. Sharps bins were closed when not in use and were not overfilled.
- The service had completed risk assessments for all new or modified use of radiation. The risk assessments addressed occupational safety as well as considering risks to people who used services and the public.
- The service had arrangements to control access to areas where there was non-ionising and ionising radiation. Where there was ionising radiation, these areas were clearly signposted with warning lights. For example, in the PET/CT scanning suite, safety standards were met for the safe administration of nuclear pharmaceuticals (radioactive medicine enabling this specific computerised tomography scan). This included restricted access by key pad only and specifically to the laboratory where the radioactive medicines were prepared. There were designated single waiting rooms for patients who had received the radioactive medicine and were waiting for their scan. The rooms were referred to as 'hot rooms' and included access to toilet facilities. Staff wore 'dose meters' to monitor exposure to radioactivity and these were audited to ensure their safety.
- All relevant MRI equipment was labelled in line with Medicines and Healthcare Products Regulatory Agency (MHRA) recommendations. Equipment displayed MRI safe, MRI conditional or MRI unsafe stickers. This made staff aware what equipment could be used around the MRI machines at both the imaging centre and on the mobile units, for example trolleys and fire extinguishers. There was also a list of equipment available to staff identifying the equipment available on the mobile units and on posters on the wall at the imaging centre. However, we found one fire extinguisher in one mobile unit which was not labelled as MRI safe in line with MHRA recommendations.
- There were systems and processes to make sure specialised personal protective equipment was available and used by staff. There were systems to check that lead aprons, lead screens and syringe shielding for PET/CT scans was not damaged.
- The service carried out assessments and reviews of their activities under the Control of Substances Hazardous to Health (COSHH) Regulations 2002 (COSHH). We reviewed COSHH risk assessments for the use of cleaning solutions for the cleaning of water dispensers, skin preparation for the insertion of intravenous devices and equipment cleaning wipes. The risk assessments were carried out in 2011. Following the inspection, we were provided with further evidence to demonstrate that COSHH assessments were carried out regularly
- Resuscitation equipment for adults was readily available. Records demonstrated the resuscitation equipment was checked monthly between January and July 2019. Staff recorded on the checklist when equipment was due to expire to ensure it was replaced. We checked randomly selected consumables which were all in date. Emergency medicines kept on the resuscitation trolley were in tamper evident packaging, intact and in date. However, we were not assured the service had taken account of all relevant sources of advice in assessing risks and managing paediatric patients safely. Staff did not have access to paediatric life support equipment in the event of a clinical emergency involving a child.
- There was an equipment replacement programme. The service had recently bought a new mobile scanner and all staff were aware that one of the MRI scanners was old and needed replacing. Senior leaders were exploring different scanner options as this particular scanner was used for patients who were afraid of confined spaces.

Diagnostic imaging

- The service had technical support for the electronic programmes it used. We saw the contract with an external company who provided the technical support. There was also a member of staff with a designated IT support role based at the imaging centre, who was available to manage problems. Staff on the mobile units could call this member of staff for help and advice.

Assessing and responding to patient risk

- **Staff completed and updated risk assessments for each patient and removed or minimised risks, however these were not documented to provide an audit trail behind the rationale for the decision.**
- Thorough and comprehensive generic risk assessments were carried out for people who used services, and these were documented. The service carried out risk assessments multiple times to ensure patient safety. We observed risk assessments being carried out consistently for all patients at three different stages of the process: initially when the patient was booked in for their appointment, again on arriving at the unit and finally just prior to their scan, when the radiographer would go through the risk assessment to confirm the answers the patient had given. This ensured there were numerous opportunities to identify risk and ensure patient safety.
- Staff at both the imaging centre and on the mobile units were confident in carrying out additional on the spot, individualised risk assessments to ensure patient safety, but these were not always formally documented. For example, if patients arrived for an MRI scan with metal jewellery which could not be removed or tattoos, they risk assessed the individual to identify whether it was safe to continue with the scan. We observed staff weigh up and discuss the risks and benefits of going ahead versus not going ahead and explaining the rationale to the patient. Staff were clearly able to verbalise their rationale. However, despite carrying out these risk assessments, they were not documented and therefore there was no record these risk assessments occurred.
- There were processes to ensure the right person received the right imaging procedure or radiological scan at the right time which was routinely completed by all radiographers working for the service. The Society and College of Radiographers (SCoR) "Paused and Checked" guidance system was used to reduce the risk of errors occurring. "Pause and check" consisted of the three-point demographic checks to correctly identify the

patient. This also included checks with the patient regarding the site to be imaged, the existence of previous imaging and for the operator to ensure that the correct imaging modality was used.

- There was a procedure which staff followed if a person deteriorated whilst visiting the service. The medical emergency (cardiac arrest) policy outlined the procedure staff must take if they were involved in resuscitation. There were local protocols for the imaging centre and posters available on the walls of the control rooms to provide guidance for staff in an emergency. Staff at the mobile units we visited were clear on the emergency procedure for their particular mobile unit. We were given an example of when staff on a mobile unit had followed their emergency procedure to manage a deteriorating patient. Between April 2018 and April 2019, there were three unplanned transfers from the service due to patients suddenly deteriorating whilst visiting the service for their investigation.
- Authorisation was sought prior to children attending the unit to receive a PET/CT scan. The service did not accept referrals for children and young people under the age of 14 years for PET/CT scans. Prior to children attending the service, authorisation had to be sought from a number of people and professional bodies. These included NHS England, the local clinical commissioning group, the medical director and lead radiologist holding the Administration of Radioactive Substances Advisory Committee (ARSAC) license. We saw evidence of the audit trail demonstrating approved authorisation from the required people.
- There was a radiation protection advisor accessible for providing radiation advice. The service had a named member of staff fulfilling this essential role who was based on site at the imaging centre. There were also radiation protection supervisors in each clinical area. The medical physics expert (MPE) was readily accessible on the telephone for providing radiation advice when required. This support was provided by a member of staff employed by an NHS hospital trust.
- There were signs or information in the radiation department waiting area informing people about areas or rooms where radiation exposure took place. Signs were located throughout the unit in both words and pictures highlighting the dangers and contraindications with scanning procedures.
- The service made sure women (including patients and staff) who were or may have been pregnant always

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informed a member of staff before they were exposed to any radiation in accordance with Ionising Radiation (Medical Exposure) Regulations 2018 (IR(ME)R). The service had a set of local rules to follow regarding pregnancy for both staff and patients. These provided clear advice and protocols about the different stages when pregnant women could or could not be scanned. Risk assessments were also completed at three different stages of the process, which covered pregnancy. The local rules around pregnancy were based on national and evidence-based guidance to ensure the safety of both staff and patients.

- There were local rules and policies available for the risk assessment and prevention of contrast-induced nephropathy. These were in keeping with NICE acute kidney injury guidelines and the Royal College of Radiologists' standards for intravascular contrast agent administration. There was a policy and guidance available for staff at the imaging centre and on the mobile units. The contrast media checklist form required staff to complete the nephrogenic systemic fibrosis (NSF) (a rare disease that occurs mainly in people with advanced kidney failure, which can be triggered by exposure to contrast agents used in MRI scanning) risks section which included a review of the patient's blood test results. The form also provided guidance regarding parameters for safe treatment.
- At the imaging unit in Cheltenham, we observed staff check when kidney function tests were last obtained, and these were repeated prior to scanning if required. The service used a small device specifically designed to test kidney function, where the result was available immediately.
- We observed contrast being used for scans at one of the mobile units we visited. A contrast prescription was drawn up by the host trust, who also carried out the required renal function testing in line with their protocol and a risk assessment to determine whether it was safe to use contrast media with the patient. Radiographers on the unit were made aware of the outcome of the renal function tests on the contrast prescription. A further risk assessment was carried out around the use of contrast media with the patient.
- Staff ensured the safety of patients when there was a requirement to administer contrast media. Radiographers used a contrast media and drug safety checklist on patients who required the use of contrast media for their scan.
- A record of the medicine given to the patient was maintained along with the time it was administered. The patient was also provided with this information on leaving the mobile unit. If for any reason the patient had to seek medical assistance once they had left the unit, in case of any adverse reaction, healthcare professionals would be aware of the medicine they had received.
- There was a process to support staff when referring a patient to a drug allergy specialist where contrast reactions were identified, or when staff needed advice and support
- There were clear processes to escalate significant findings. Staff were clear on the procedure they would follow if there were significant findings and mark the record as urgent and call the radiologists to alert them. Staff also told us that if there was anything unexpected identified, they could call the radiologists to view the scan whilst on the telephone to see if they could do anything additional. For example, additional scans or use a contrast media to save the patient having to return for further scans. This would reduce the likelihood of delays for the patient to access treatment. Staff were able to provide examples of when this scenario had occurred and the actions they had taken.
- There were procedures for the collapse of a patient when in an MRI scanner. Practice drills took place at the imaging centre. Staff from the mobile units would also attend the unit to carry out the practice drills. Drills took place twice a year. Following each drill, a report was written up detailing the observation, outcomes and recommended actions. This was circulated to all staff to support their knowledge and learning. We saw evidence the outcome of a drill was discussed at a staff meeting in June 2019. Staff stated these drills were valuable and addressed different scenarios, such as the safe evacuation of a deteriorating patient from an MRI scanner or mobile unit. Staff were knowledgeable about the correct procedures to take to ensure the safety of the patient and staff, including additional staff from the host trust of mobile scanning units.
- There were local rules (IRR) and employers' procedures (IR(ME)R) which protected staff and patients from ionising radiation. The local rules were available at the imaging centre and on the mobile units in paper form. Staff also had access to these electronically.
- There were effective arrangements in case of a radiation or radioactive incident occurring, such as radioactive spillage while carrying out a PET/CT scan. There was

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guidance available and a designated spillage kit. Staff told us of how they had safely managed an incident of a small spillage of radioactive medicine. The room where the incident occurred was taken out of action until the radiation exposure was within safe limits.

Radiographer staffing

- **There were sufficient numbers of staff with the necessary skills, experience and qualifications to meet patients' needs.** Actual staffing levels and skill mix compared well with the planned and required levels. The staffing protocol ensured the service operated safely, with the appropriate number of staff and correct skill mix levels required to facilitate safe care.
- The service had a procedure to identify safe staffing requirements. There was no national guidance about safe staffing for diagnostic imaging services. However, the service had developed its own minimum radiographic staffing level protocol.
- The protocol identified the PET/CT scanner must be operated by two PET/CT trained radiographers competent in PET/CT scanning procedures. The MRI scanners required one fully trained radiographer, supported by a second radiographer, MRI trained assistant practitioner or radiographic assistant. When located offsite, the minimum staffing requirement for the mobile MRI scanners was two members of staff at all times. This included one fully qualified MRI trained radiographer and either a second qualified MRI trained radiographer, MRI trainee radiographer, MRI trained assistant practitioner or radiographic assistant. There were also specific requirements for minimum staffing for the CT scanner, X-ray and core beam computerised tomography (CBCT).
- As of May 2019, there were a small number of staff vacancies within the service. There were 6.5 full time equivalent (FTE) vacancies for radiographers, a 0.8 FTE vacancy for radiographer assistants and 1.8 FTE vacancies for administrative support. Senior staff identified staffing as a challenge. Senior leaders told us recruitment was an ongoing challenge. Work was ongoing to explore what was needed to attract radiographers to work for the service. This included providing bursaries to students.
- Agency staff were used to cover unfilled shifts. Between February and April 2019, agency radiographers had covered 252 shifts and agency administration staff had

covered 172 shifts. During these three months, agency staff had covered shifts for the 2.9% average sickness rate of radiographers and 0.9% average sickness rate for administration staff. Agency staff completed an induction checklist which was kept by the provider.

- There was clear guidance for staff regarding lone/unaccompanied working mainly for staff working offsite on the mobile MRI/CT units. Staff working on the mobile units were very clear about this policy and the information it contained. The minimum staffing protocol set out action staff needed to take when faced with different scenarios. All staff on the mobile units were aware of the risks involved with the work they carried out and would not see patients alone. They were able to clearly discuss the risks with lone working on the mobile units. This ensured the safety of both staff and patients.

Medical staffing - Radiologists

- **The service had enough medical staff with the right qualifications, skills, training and experience to keep patients safe from avoidable harm and to provide the right care and treatment.** Medical staffing was provided by a local NHS trust. The service purchased 10 consultant radiologist programmed activities, each providing four-hour sessional cover on a weekly basis. This made sure there was a radiologist on site for a large proportion of the week to provide expert medical advice. Additional radiology sessions were also secured from another external company to provide additional radiology reporting on site to meet demand.
- Medical staff worked at the imaging centre under practising privileges. Practising privileges are when medical practitioners are granted permission to work in an independent hospital, clinic, or service. A system had been implemented to ensure medical staff only carried out work they were skilled and insured to carry out. Information requested and held by the service included indemnity insurance, information about appraisals, revalidation and registration with the General Medical Council.

Records

- **Staff kept electronic records of patients' care and treatment.** Staff entered relevant information into patients' electronic records and scanned in paper documents to ensure all information was available to staff. Scanned records were destroyed to ensure patient confidentiality.

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- Patients' personal data and information was kept secure and only staff had access to the information. Staff received training on information governance as part of their mandatory training programme.
 - The service used the radiology information system (RIS) and picture archiving and communication system (PACS). These were secure, and password protected. Each staff member had their own personally identifiable log in.
 - Information needed to deliver safe care was available to relevant staff in a timely and accessible way at the imaging centre and on the mobile units. This included referral information, previous imaging results and test results if required.
 - Staff recorded any additional comments or information which may be of use or required by the radiologist reading the images on the electronic system. Additional risk assessments or consent forms which were paper based were scanned onto the electronic system and held with the patient's electronic record following their appointment. Staff completing the scan updated the electronic records and submitted the scan images for reporting by the relevant organisation.
 - There was limited documentation of additional information regarding patient care. For example, staff did not record when patients left the unit following administration of contrast media, that cannulas were removed, and that post scan care information had been given to patients and their next of kin. Patients receiving contrast were advised to stay in the waiting room for 30 minutes following the scan. However, this was not recorded unless patients declined and left straight away following their scan.
- Medicines**
- **The service used systems and processes to safely prescribe, administer, record and store medicines. However, the Patient Group Directions (PGDs) used by the service did not have the required authorisation as recommended by national guidance.**
 - A record of the medicine given to the patient was maintained along with the time it was administered. If for any reason the patient had to seek medical assistance once they had left the unit, in case of any adverse reaction, healthcare professionals would be aware of the medicine they had received. The patient was also provided with this written information on leaving the mobile unit.
 - Contrast media and other medicines were stored securely. Contrast media was stored in locked cupboards to which only radiologists had access. We reviewed the expiry dates for some of these and found them all to be in date and in intact packaging. There were processes to log each contrast media given to patients. This ensured the patient could be traced if required.
 - Patient Group Directions (PGDs) were not used in accordance with The Human Medicine Regulations 2012 regulation. This meant these were given without a prescription or authorisation. A Patient Group Direction (PGD) is defined by the National Prescribing Centre (2004) as 'a written instruction for the sale, supply and or administration of named medicines in an identified clinical situation'. The service used five PGDs for medicines. However, none of these had been signed off by a pharmacist and two were not signed by the additional authorised people as recommended. Also, there was no PGD for the use of saline when giving medicines or radioactive tracers intravenously. Following the inspection, the senior team informed us the medical director was engaging with a pharmacist to ensure the right authorisation was sought to meet the legislation.
 - Emergency medicines were available in the event of an anaphylactic reaction. The local NHS trust provided pharmacist support and supplied anaphylaxis and other medicines as required following signed requests from the medical director. No controlled drugs were stored or administered by the service.
 - Radioactive tracers were ordered from an external source daily and prepared overnight before being dispatched and delivered each morning by designated couriers. The radioactive tracers were stored within lead lined containers and locked into a designated crate, which was protected by a safety code. The code was shared with the service via email each day. There were processes for signing radioactive tracers in and records maintained to identify all unused tracers.
 - Contrast and radioactive medicines were prescribed by radiologists. Contrast medicines were prepared and checked by two radiographers before they were

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administered as part of the scans for which they were required. Radioactive tracers were administered through a designated pump designed to administer the correct dosage to patients.

- The service ensured the Medicines (Administration of Radioactive Substances) Regulations 1978 (MARS), were taken account of. PET scanning was performed with access available by telephone to either an administration of radioactive substances committee (ARSAC) license holder or their delegates. We saw evidence of the licence which was held by the lead consultant and the imaging centre also maintained a copy. We also saw evidence of the environmental agency permit which supported the safe removal of radioactive clinical waste.

Incidents

- **The service managed patient safety incidents well. Staff recognised and reported incidents and near misses. Managers investigated incidents and shared lessons learned with the whole team and the wider service.**
- Staff were aware of their responsibilities to raise concerns, record safety incidents and near misses and report them internally. There was an incident reporting policy and pathway to enable staff to report incidents or near misses. The policy outlined the responsibilities of the staff in reporting incidents and provided information about the procedure to report incidents. Staff explained the procedure of reporting incidents electronically at the imaging centre, and the paper incident reporting process in use on the mobile units.
- There had been no never events between April 2018 and April 2019. Never Events are serious, largely preventable safety incidents that should not occur if the available preventative measures are implemented.
- There had been no serious incidents or IR(ME)R/IRR reportable incidents at the service between April 2018 and April 2019. Serious incidents can be identified as an incident where one or more patients, staff members, visitors or member of the public experience serious or permanent harm, alleged abuse or a service provision is threatened.
- Staff received feedback about incidents which had occurred. Staff were able to give examples of incidents and the actions they now took as part of their practice as a result of the incident. Staff at the imaging centre and out on the mobile units told us incidents were

discussed at staff meetings and information was also provided to them by email to ensure staff working in the field on the mobile units remained up to date with important information about incidents. We reviewed the minutes from the staff meeting in June 2019 which included a list of incidents which were discussed.

- There was a process to make sure radiation incidents were fed into risk management. For accidental and unintended exposures, processes included notification to CQC under IR(ME)R or to HSE under IRR requirements. We saw an example of an incident involving radiation in July 2019, prior to our inspection. We saw evidence the incident was promptly discussed with the radiation protection advisor (RPA) from the NHS trust which supported the service to determine whether it was internally or externally reportable. Once this had been clarified, the service said they would notify the correct professional bodies.
- The duty of candour is a regulatory duty that relates to openness and transparency and requires providers of health and social care services to notify patients (or other relevant persons) of 'certain notifiable safety incidents' and provide reasonable support to that person. There was a duty of candour policy which provided guidance and examples of incident events which would be recognised as a duty of candour trigger. The policy also provided information for staff regarding the duty of candour pathway. There had been no requirement to implement the duty of candour between April 2018 and April 2019.

Are diagnostic imaging services effective?

Effective means that your care, treatment and support achieve good outcomes, helps you to maintain quality of life and is based on the best available evidence.

We do not currently rate effective for diagnostic services due to insufficient data being available to rate these services' effectiveness nationally.

Evidence-based care and treatment

- **The service provided care and treatment based on national guidance and evidence-based practice. Managers checked to make sure staff followed guidance.**

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- There were processes to ensure 'local' rules were reviewed and updated regularly. The service made sure it identified and implemented relevant best practice and guidance, such as National Institute for Health and Care Excellence (NICE) guidance. We reviewed a set of protocols known as 'local rules' for different processes/ scans carried out by the service. The local rules were evidence-based, version controlled and reviewed regularly. For example, there was an implant and device policy which was written in April 2019 and due a further review in April 2020. The local rules included a reference list to support the evidence and guidance which had been used to develop the local rules.
- The service ensured guidance from the Faculty of Clinical Radiology (FCR) for the communication of radiological reports was followed. There was a standard operating procedure which stated the reporting time for scans carried out at the imaging centre in Cheltenham. Radiologists reviewed and reported on scans daily and some reports were reviewed and signed off by two radiologists. There were processes for radiographers to refer scan results for immediate interpretation where there were unexpected scan results, in line with standards one to three of the guidance. Scans carried out on the mobile scanning units were sent electronically to the host hospital. Staff were advised to inform patients when they could expect the results of the scan.
- The service ensured the Ionising Radiation (Medical Exposure) Regulations 2018 (IR(ME)R) were adhered to. There was an administration of radioactive substances committee (ARSAC) certificate holder (the medical director for the service).
- The service used the diagnostic reference levels (DRLs) as an aid to optimisation in medical exposure. Data was collected and audited to ensure radiation doses remained as low as reasonably practicable in accordance with IR(ME)R guidelines 2017. Data was submitted monthly to the radiology protection services provided to by an NHS trust to monitor DRL. DRLs were benchmarked against other services and a report was produced yearly following a review of the data provided by the unit. The report which covered January to December 2018 identified one area which needed to be reviewed. There was no corresponding action plan for the management of this recommendation, nor was there documented evidence this recommendation had been acted on.

Nutrition and hydration

- **There were arrangements to provide access to food and drink for patients at the imaging centre in Cheltenham.** Snacks and drinks were available in the reception area for patients at the imaging centre. Tea, coffee and chilled water was available and free of charge. There was also a fridge with a selection of alternative drinks, which patients could buy. Snacks and fruit were also available for patients to purchase.
- The service took account of people living with diabetes when they were required to attend for fasting examinations/scans. The booking staff spoke with patients and asked for their preferred time to attend for scans if they were required to fast in preparation.

Patient outcomes

- **Staff monitored the effectiveness of care and treatment in line with contractual arrangements with commissioners. 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 participated in the Quality Standard for Imaging (QSI), formerly the Imaging Services Accreditation Scheme (ISAS). The service was accredited for its imaging centres and its mobile units and received this accreditation in September 2018. It was due for renewal in October 2022. This enabled the service to benchmark against national standards and constantly review and improve service provision.
- The service was also working towards Cyber Essentials Plus (CE+) accreditation (technical controls to help organisations protect themselves against common onlinesecuritythreats). Work was ongoing at the time of this inspection to meet the standards required to become accredited. The service aimed to become accredited in September 2019. The service had also achieved the ISO 9001:2015 quality management standard. This was an accreditation of their quality management systems which demonstrated their ability to consistently provide evidence to support compliance with applicable statutory and regulatory requirements.
- The service collected data around their performance. The service worked towards monthly key performance indicators (KPIs) for MRI and PET/CT. The KPIs included contacting patients within five days of acceptance to the

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service for MRI scans and sending reports for review within five days of a patient's scan. See the access and flow section under responsive for further detail round KPIs and performance.

- Information was collected for the commissioners to provide oversight of how the service was performing in relation to key performance indicators such as report writing times, patient waiting times and cancellation of scans. Data was collected monthly from several internal audits and a quarterly report was submitted to the commissioners. This provided commissioners with information on activity and any issues impacting on service provision such as staffing, equipment, operational issues and improvements.
- There were processes for peer feedback and QA of reports. Radiologists reviewed and reported on scan results and these were sampled by a second review by another radiologist to ensure quality. All PET/CT scans were reported on by two radiologists before the results were shared with the referring clinician.

Competent staff

- **The service made sure staff were competent for their roles. Managers appraised staff's work performance.** Staff who administered radiation were appropriately trained. Staff who were not formally trained in radiation administration were adequately supervised in accordance with legislation set out under IR(ME)R.
- Staff working with radiation had appropriate training in the regulations, radiation risks, and use of radiation. Staff were able to provide evidence of training and were aware of the Ionising Radiation Regulations 2017 (IRR17) and the Ionising Radiation (Medical Exposure) Regulations 2017 (IR(ME)R). Records identified all staff who required this training had completed this. Staff had also completed competencies within the requirements of their role and responsibilities on joining the service.
- All radiographers held immediate life support qualifications, and these were renewed annually.
- Cannulation audits were completed yearly to ensure staff remained competent to carry out this aspect of their role. Competencies were completed and signed off when radiographers started working for the service. Staff were then required to do a yearly self-audit of 20 cannulations to evidence their competence. This was then followed up every three years with an observed competency assessment, which was signed off by senior staff. Staff were responsible to report any concerns they had regarding their competence in this area and seek additional support and training as part of their professional code of conduct and responsibilities.
- Staff received an induction on starting employment with the service. New employees attended a corporate and local induction covering rules, processes and procedures. This made sure new employees understood how the service worked and their expectations of employees. We spoke with staff who had recently been employed who stated their induction had been thorough and informative.
- Agency staff working for the services underwent a series of check to ensure they were competent to work for the service. Agency staff were also provided with corporate and local inductions. These inductions covered the local rules, processes, and procedures, which provided the member of staff with greater understanding of the role, service and expectations. Agency staff told us they had found the three-day induction informative. They felt supported by having the opportunity to work alongside established staff to ensure they worked in accordance with Cobalt Health's values and expectations.
- Staff were supported and encouraged to develop. All MRI staff attended in-house Cobalt Health MRI radiographer training. This training had been recently developed by the training lead and broken down into modules which staff completed, to make this more accessible. Competencies were signed off as staff became competent in their knowledge and skills in a specific area. There were plans to develop this in-house training programme for PET/CT in the future.
- Staff had additional opportunities to attend training to enhance their knowledge and skills. Radiologists from the local NHS trust arranged evening training sessions where staff were invited to attend. For example, an orthopaedic consultant had presented a session on the shoulder joint. This had provided information to the radiographers as to what the consultant would look for from the scans and provided more information on conditions and disease processes.
- There were arrangements to make sure the service was informed if a staff member from an NHS trust was suspended from duty. There were processes to ensure the local NHS trust informed the service if any of the radiologists working under practicing privileges were suspended from the usual place of working.

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- Most staff had received an annual appraisal. There was 100% compliance with appraisals for superintendent radiographers (two staff), and 96% (24 of 25) radiographers had received their appraisal. Of the radiography assistants, 89% (eight out of nine staff) had received their appraisal, along with 72% of administration staff (31 of 43). Staff told us appraisals were useful and helped them to identify their training and development needs.

Multidisciplinary working

- **All those responsible for delivering care worked together as a team to benefit patients. They supported each other to provide good care and communicated effectively with other services.** The service hosted a team of multidisciplinary healthcare professionals from the local NHS trust to provide one-stop screening services for patients presenting with musculoskeletal complaints. They supported the service with imaging or scans to ensure patients could receive a diagnosis and treatment during one appointment.
- Staff were appropriately involved in assessing, planning and delivering patients' care. Staff worked closely with the referring NHS trusts, to ensure a smooth pathway for patients.
- Staff could access patients' previous scans and images. Booking staff asked patients as part of the booking process, if they had had previous scans. Radiographers and radiologists could access these scans to ensure similar protocols were used in order that scans/images could be compared.
- The service had good relationships with other external partners and undertook scans for local NHS providers and clinical commissioning groups (CCGs). We saw evidence of good communication between services and there were opportunities for staff to contact referrers for advice and support. Staff on the mobile units spoke highly of the support they received from the host NHS trusts. Staff from the host trusts also spoke of positive relationships with the radiographers on the mobile units and with the staff at the imaging centre headquarters in Cheltenham.

Seven-day services

- The imaging centre was operational from 8am to 7.30pm Monday to Friday and operated a Saturday morning service. Additional services could be provided to manage an increase in demand on a Saturday

afternoon and a Sunday, if the service was able to find staff to cover the shifts. The mobile units operated between Monday and Friday. Services ran from 8am and finished at either 6pm or 8pm depending on the contract provision requirements for the NHS trust the mobile unit was supporting.

Health promotion

- Information leaflets about the patient's scan were sent along with their appointment letters. Further information was also available in the reception area. These leaflets included information about what the scan would entail and what was expected of the patient before and after the scan appointment.

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.**
- Staff understood the relevant consent and decision-making requirements of legislation and guidance, including the Mental Capacity Act 2005. Staff received training on mental capacity and there were posters on the walls around the imaging centre to remind staff of the principles and their responsibilities.
- Some imaging was consented for using implied consent. The risk assessment which patients completed required them to confirm whether they understood the reason for their scan and the risks associated with this. Consent was implied, which meant that if a patient continued to move forwards with the procedure as instructed by the radiographers then they would continue with the scan. Staff told patients they could request to stop the scan at any stage and we observed this happening. Staff also provided us with examples where patients had not been able to progress through the different stages to prepare for the scan due to fear and anxiety. On occasions like this, it was deemed by the radiographers as not having consent to continue, which they respected.
- There were procedures to ensure imaging was properly consented for when required. Where contrast media was required, patients were asked to provide written consent. Information was sent to patients alongside their appointment letter to ensure they had sufficient knowledge to give informed consent for scans.

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- Staff were aware of what to do if they had concerns about a patient and their ability to consent to the scan. They were able to clearly tell us what they would do if they were faced with this situation and how they would manage this for the patient. They would make the referrer aware of their concerns, and it would then be for a radiologist to determine their suitability to receive the intervention.
- Staff demonstrated their understanding around mental capacity and decision-making processes. A patient attended the service who had fluctuating capacity. The patient attended with a relative who provided support to the patient. Staff were able to demonstrate and verbalise how they had come to a decision that they would continue to scan the patient. However, this decision-making process was not documented.
- Staff demonstrated a supportive attitude to patients at the unit. Staff used appropriate humour to engage with patients and thereby help to alleviate patients' anxiety if required. Staff ensured patients had a call bell, so they could call for assistance if required. During scans, staff frequently interacted with patients using an intercom system.
- Staff worked to maintain patient comfort during their scan. Staff consistently checked patients were as comfortable as they could be. Staff recognised when patients needed extra support. For example, a patient who started to cough when laying down was given an additional headrest to improve their comfort.
- All patients we spoke with talked positively about the care provided by the unit staff. Patients told us staff were kind and explained "all I needed to know about the scan" and spoke about staff "going the extra mile."
- Staff introduced themselves to patients and explained their role. This was in line with NICE QS15 Statement three: Patients are introduced to all healthcare professionals involved in their care and are made aware of the roles and responsibilities of the members of the healthcare team.
- Staff treated children, young people and their families with compassion and kindness, respected their privacy and dignity, and took account of their individual needs. We observed staff on one of the mobile units care for and provide a diagnostic scan to a young person. The young person was treated with kindness and respect. Staff supported their next of kin to be present in the scanning room during the scan following appropriate risk assessment in line with their policy. This helped the young person to feel less anxious about the scan.

Are diagnostic imaging services caring?

Good 

Caring means that staff involve and treat you with compassion, kindness, dignity and respect.

We rated caring as **good**.

Compassionate care

- **Staff treated patients with compassion and kindness, respected their privacy and dignity, and took account of their individual needs.**
- We observed staff to be kind and compassionate in the way they interacted with patients. Staff took time to interact and answered questions in a kind manner ensuring patients understood the information they shared. This met NICE QS15 Statement two: Patients experience effective interactions with staff who have demonstrated competency in relevant communication skills.
- Care observed met National Institute for Health and Care Excellence (NICE) QS15 Statement one: Patients are treated with dignity, kindness, compassion, courtesy, respect, understanding and honesty. There were areas where the patient could get changed if necessary. Patients could also be provided with gowns to maintain their privacy and dignity. We observed staff always take care to maintain patients' privacy and dignity.

Emotional support

- **Staff provided emotional support to patients, families and carers to minimise their distress.** Staff understood the impact that a patient's care, treatment or condition had on their wellbeing and on their relatives, both emotionally and socially. Staff spoke clearly and could empathise with patients who attended the service for a scan. They were understanding of the emotions, anxieties and fears patients faced when attending the service and provided support.
- Patients attending for PET/CT scans were given verbal and written information after their scan to ensure they fully understood risks following the radioactive tracers

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given to them for their scan. Some patients were anxious about this, but staff took time to reassure and explain the risks and the precautions they were required to take.

- Staff were aware of the needs of the patients attending the service. They could tell if they were upset or anxious and did their best to support and comfort them. Staff told us they did what they could to overcome the patient's anxieties to make sure the patient could go ahead with their scan during the appointment to prevent them having to return to the service. Staff recognised scan-related anxiety could impact on diagnosis for patients and cause possible delays in further treatment.
- Staff provided support and reassurance to emotional patients. We observed staff tend to patients who were emotional about undergoing their scan. In these situations, staff were calm and took their time to reassure the patient. They broke down what was happening, stage by stage, and maintained communication with the patient throughout the scan.
- Staff provided ongoing reassurance to patients throughout the scan. They updated the patient on how long they had left in the scanner and what they could expect with regards to the noise the scanner would make.
- Staff understood and supported patients who suffered from claustrophobia during scans. Staff took time to explain the scan procedure and took time to ensure patients were comfortable before leaving the scan room. When possible, staff chose the least claustrophobic scanning process possible and reassured patients could call for help and that the scan would be stopped immediately. During scans, we observed staff talk with patients and provide reassurance. They told patients how long the next scan would take and so on. Staff offered patients the opportunity to listen to music during scan as a way of taking the mind of the scanning process.

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 engaged with patients and provided support to ensure patients understood what was going on before the scan, during the scan and when patients left the service.

- Staff communicated with patients to ensure they understood their care and condition. They took the time to explain the procedure and what would happen during their appointment. Staff gave clear instructions of when the results would be available and asked patients to make an appointment with the referring practitioner to discuss the result of their scan and any ongoing treatment if required.
- Staff understood the importance of involving family members and close relatives as partners in patients' care in line with NICE QS15 Statement 13: Patients' preferences for sharing information with their partner, family members and/or carers are established, respected and reviewed throughout their care. The service allowed for a parent, family member or carer to remain with the patient for their scan if this was necessary. This helped to calm some patients' nerves and anxieties about their scan.
- Staff recognised when patients and their relatives needed additional support to help them understand and be involved in their care and enable them to access this. Patients and those close to them were given written information about scans and could ask questions about their scan. We observed staff giving patients and their relatives time to ask questions, and when they did, they were answered clearly to ensure understanding.

Are diagnostic imaging services responsive?

Outstanding



Responsive services are organised so that they meet your needs.

We rated it as **outstanding**.

Service delivery to meet the needs of local people

- **The service planned and provided care in a way which was tailored to meet the needs of local people and the communities served. The service also worked with others in the wider system and local organisations to plan care.**

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- Patients individual needs were central to the planning and delivery of tailored services. The service worked with NHS specialised commissioners to provide a PET/CT service for a population of two million patients across the south west and Midlands.
- The involvement of other organisations and the local community was integral to how services were planned. The service was committed to ensuring timely access to diagnostic scans for patients to enable timely access to care and treatment. This helped to improve patient experience. The service provided 800 diagnostic procedures for the local NHS trust as a charitable donation to support them with waiting times and patient experience.
- The service worked with local partners to increase their capacity to improve patient experience and support system-wide working. For example, the service provided facilities to a local NHS trust to enable timely access for patients to the breast screening programme. Also, the service provided facilities for local consultants to provide one-stop clinics for musculoskeletal patients to enable them to receive their scan and ongoing care and treatment during the same appointments.
- The services provided reflected the individual needs of the population served and ensured flexibility, choice and continuity of care. There were out of hours and weekend services provided for patients. Services were provided at the imaging unit and in the mobile units five days a week, and on a Saturday morning. Patients were also able to access appointments outside of working hours as the imaging centre and some mobile units were open 12 hours a day.
- In instances where demand increased, the service provided extra capacity by offering additional services at the weekend at the imaging centre in Cheltenham. This was dependent on whether safe staff levels could be secured for the additional requirements of the service, because weekend working was voluntary for staff. However, we were told there was never a problem with staff volunteering for additional shifts.
- Services were delivered from various locations to bring care closer into the local community for patients. Patients could access the imaging centre in Cheltenham and the mobile units. The mobile units moved between regions as required.
- There was involvement of other organisations, and system wide working to meet people's individual needs. The service was able to support NHS trusts to manage their capacity and demand challenges to improve waiting times for patients. The week following our inspection, the service was providing a mobile CT scanner to support an NHS trust to provide CT scans to help improve cancer waiting times for patients.
- Services were delivered in a way which promoted equality and supported patients with complex needs. The service had the facility to scan patients who were less mobile, to make the process easier for them. The service provided a Cone Beam CT scanner. This machine was easier to access for less mobile patients and the machine moved to accommodate the patient. Uptake for this type of scanner was not as popular as other modalities provided by the service. However, the scanner was due to be used to support a scaphoid study (one of the eight bones which makes up the bones of the wrist) as part of a research study. This was in the planning stages at the time of our inspection.
- The environment was appropriate, and patient-centred. The imaging centre had facilities for 'cold' patients (who did not receive radioactive tracers) and 'hot' patients (who received radio radioactive tracers). There was a waiting room for 'cold' patients, with a variety of seating, including chairs with arms. There were also three 'hot' waiting rooms, one larger than the other two to accommodate non-ambulant patients.
- Patients were provided with information prior to their appointment so they knew what to expect when attending the unit. Information included directions to the imaging centre, information about the scan they were having, how to prepare for this and what would happen during the appointment. Written information and explanations on aftercare were also given after examination. For example, cannulation sites and hydration, what to do in the event of feeling unwell and how and where patients could get the results of their scans.
- There was sufficient car parking available for patients. At the imaging centre, there were 31 spaces available for patients, including three disabled spaces. Parking was free of charge for patients visiting the centre.
- The department was clearly signposted for patients. Once patients were called in for their appointments, they were always accompanied by staff.

Meeting people's individual needs

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

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was an innovative approach to providing integrated patient-centred care. Staff made reasonable adjustments to help patients access services. They coordinated care with other services and providers.

- There was a proactive approach to understanding the needs of different patient groups to enable service to be delivered to meet their individual needs. Reasonable adjustments were made so disabled patients could access and use services on an equal basis to others. The imaging centre was spread over two floors. Patients could either use the stairs or the lift to access the floor they required. There were disabled toilet facilities, wheelchair availability and a variety of chairs in the waiting room suitable for patients with differing physical needs.
- The needs of individual patients were also proactively managed on the mobile units to ensure equality and equal access to local services. Disabled patients or patients with mobility problems could also access the mobile units via the lift mechanism on the vehicles. We observed this in use during our visit to one of the mobile units.
- The service understood the needs of patients who attended who were in vulnerable circumstances or who had complex needs. There was a system for managing the needs of patients living with dementia or a learning disability. There was a system on the referrals process to identify these patients. This meant additional time could be added to the patient's appointment to give the patient time to understand and get used to the environment and what was required of them. Staff told us in these situations they worked closely with the patient and their relative/carer to get the best for the patient and the appointment. Staff were able to give us examples of when they had done this.
- The service met the needs of vulnerable service users such as patients with learning difficulties or dementia. These patients could bring a relative or carer to their appointment as support. Patients and relatives could be present in the scanning room if required.
- We observed staff being responsive and supportive to a patient with mental health problems who had accessed the service. This patient and their family member were given additional time to ensure all aspects of the appointment were carried out. We saw how staff were supportive of the patient, and also of their family member who was visibly concerned and anxious as to how the appointment would go for their loved one.
- Staff were very experienced in the management of patients who were anxious regarding the scanning process or who suffered with claustrophobia. The service provided an open MRI scanner for severely claustrophobic patients and received referrals from across the UK for this service. There was also a specific set of local rules providing guidance for staff to support them to manage patients who were claustrophobic. We observed staff being extremely responsive to these patients to ensure they had the best experience they could despite their anxieties. We saw how staff tried to call the patient and their anxieties and how they supported them when emotionally the situation became too much for the patient. The service was able to accommodate bariatric patients.
- Scanning areas and machines used advanced technology to help reduce patient anxieties. Equipment included wide bore systems, ambient lighting and soft-tone MRI gradient scanners for reduced noise for anxious patients and children. At the imaging centre, lighting in the scanning rooms could be chosen by the patient. One of the scanners also had a facility for patients to choose a video to watch for the duration of the scan to take their mind off the procedure. Patients were also provided with headphones, so they could hear the sound which accompanied the video. There was the facility to provide ambient lighting on some of the newer mobile scanners. On the mobile units, patients were also given the option to listen to the radio to drown out the loud noises of the scanners.
- During scanning, staff made patients comfortable with padding aids, ear plugs and ear defenders to reduce the noise of the MRI. Patients were provided with an emergency call alarm in case of the patient experiencing any distress. Microphones were built into the scanner to enable two-way communication between the patient and staff. Staff also recognised when patients were anxious and tried to liken the experience they were going to have with everyday events to try and keep patients calm.
- The service took account of patients' individual needs. Staff delivered care in a way which took account of the needs of different patients on the grounds of age, disability, gender, race, religion or belief and sexual

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orientation. The service offered multilingual interpreters, provided information for patients in different languages and in large print, and provided a hearing induction loop for patients.

- Refurbishment work was due to take place in the waiting area of the imaging unit. A major part of the work included relocating the check in desk to improve privacy and confidentiality for patients attending the imaging centre. The work was due to be completed by Christmas 2019. There would be no disruption to services as a result of the refurbishment. Alternative check in and patient waiting areas had been identified to keep patients away from the renovation work until its completion.

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 exceeding national standards.**

- In instances where demand increased, the service provided extra capacity by extending the working day and offering services at the weekend (seven-day access) at the imaging centre in Cheltenham and via their mobile fleet of MRI and CT scanners.
- Same day and next day appointments were available for patients as required. Referrals were received from a variety of referrers via email, fax or post. Referrals were categorised as either routine or urgent. There was a vetting process where all referrals were prioritised according to clinical need. Flexible urgent / high priority appointments were available, allowing access for urgent patients when required. The vetting was carried out by the radiographers within 24/48 hours. They would determine the scanner and the amount of time required to carry out the appointment.
- There was a process to book patients in for their appointments. Patients were telephoned by the administration team to be offered a choice of days and times for their appointments. If the patient did not respond to the telephone call within 24 hours, a letter was sent to the patient. Patients would then be given three months to respond to make their appointment.
- The administration staff carried out initial screening of patients to ensure a seamless service could be provided for patients to support access and flow through the service. This made sure patients who were attending for

an MRI scan or PET/CT had no risk factors that might have meant they were not able to receive their scan on the day of their appointment. If patients answered yes to questions which were categorised as a risk to receiving their scan, the administrator called the radiographer for support and advice. The administration staff were provided with training, so they were competent to ask the safety questions. They were also provided with additional paperwork to provide more detail and rationale for the questions they were asking.

- Patients could request a text message to remind them about their appointment 24 hours in advance. This reduced the likelihood of patients not attending or forgetting their appointments.
- The service was exceeding the six-week diagnostic test national standard. The service was meeting its 95% standard ensuring patients underwent their MRI and CT scans within four weeks of referral. The current year to date figure for 2018/2019 was 98%.
- The service was almost achieving its local key performance indicator for contacting patients within five days of acceptance to the service for MRI scans. In both April and May 2019, 98% of patients were contacted within five working days of acceptance to the clinic against a target of 99%. In April and May 2019, the reason for the small number of patients not being contacted within five days included four patients being subject to a delay in booking appointments.
- The service was almost achieving its aspirational target for MRI reports being sent within five working days of the patient's scan. In both April and May 2019, 97% of reports were sent within five days of the patient's scan, against a target of 99%.
- Between April 2018 and April 2019, 466 appointments had been cancelled due to a non-clinical reason. The main reasons for these cancellations included delays in tracer delivery, scanner breakdown or mobile vehicle breakdown. This equated to just 0.7% of the total number of patients booked annually. Of these 466 appointments, 290 were due to equipment failure, however, appointments were moved to either later in that day or to another appointment that best suited the needs of the patient. Vehicle breakdown attributed to 17 of the cancelled appointments.
- Between January and May 2019, between 198 and 225 patients were attending the PET/CT services each month. In these months, referral to report turnaround time ranged between 5.2 and 5.91 days. A small number

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of patients experienced a referral to report turnaround time of over seven days. This ranged between six and 15 patients between January and May 2019. The main reason for this was due to scanner breakdown, capacity issues due to increase in referral demand and failure or delay of the radioactive tracer.

- The service had very few patients who did not attend (DNA) their appointment. In April 2019, out of 1,695 patients, 28 (1.7%) did not attend their appointments. In May 2019, out of 1,888 patients, 31 (1.6%) did not attend their appointments. The main three reasons for DNAs were; the patient was unwell, they forgot about their appointment or they cancelled too late.

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.**

People using the service knew how to make a complaint and felt they could raise any concerns with the clinical staff. The complaints procedure was made available to patients. This was available and on display in the reception area at the imaging centre.

- There was a comprehensive complaints procedure to ensure all complaints were handled effectively. There was a complaint policy available for staff. The policy outlined there was to be an acknowledgement of a complaint within one to three days, followed by a full written explanation and response to a complaint within 20 working days. Between April 2018 and April 2019, the service received 31 complaints. Of these, 15 were dealt with under the formal complaints procedure and six were upheld.
- The service maintained an electronic record of all complaints received. Trends and themes of complaints included the quality of the images taken, communication and care and treatment by the service.
- Complaints were handled effectively to ensure openness and transparency, confidentiality, regular updates for the complainant, and a timely response and explanation of the outcome. We reviewed two responses to complaints. Complainants received a full written response which contained an apology, findings against each issue raised by the complainant, and any actions which may have been taken following the investigation of the complaint.

Are diagnostic imaging services well-led?

Good 

Well-led means that the leadership, management and governance of the organisation make sure it provides high-quality care based on your individual needs, that it encourages learning and innovation, and that it promotes an open and fair culture.

We rated it as **good**.

Leadership

- **Leaders had the integrity, skills and abilities to run the service. They understood and managed the priorities and issues the service faced. They supported staff to develop their skills and take on more senior roles. However, they were not always visible on the mobile units for patients and staff.**
- There was a clear leadership structure which demonstrated communication pathways from board to department and vice versa. Information was cascaded to staff in twice-yearly newsletters and through departmental meetings. All staff were aware of whom they reported to and of their role in the organisation.
- Senior leaders working in the service were radiographers by background and had experience from holding a number of posts within the field throughout their careers. During discussions with the senior leadership team, they demonstrated an enthusiasm and passion for their role, their department and the service as a whole.
- Staff spoke highly of their managers and the senior team. Staff told us leaders were approachable and supportive. Staff working on the mobile units felt supported by leaders and stated they were always available to provide guidance and support if required.
- Leaders were visible and approachable at the imaging centre, but not always at the mobile units. Staff at the imaging centre told us they often saw the senior leadership team and described them as personable, friendly and approachable. However, staff on the mobile units did not see the senior leadership team as they did not come to visit the mobile units. They did, however, speak highly of one of the superintendent radiographers whose role was working across the mobile units and acted as the link between staff in the field and the

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imaging centre. Despite the senior team based at the imaging centre not being visible on the mobile units, staff told us there was always support available on the telephone if they needed it. One of the senior leaders carried out one clinical shift a month when there was a mobile unit based in Hereford.

- Leaders of all levels understood the challenges to good quality care and were able to identify actions to address them. For example, we were told that bringing in radiographers from the field was challenging due to them being geographically spread and keeping them up to date. However, there were several ways staff could be brought back into the imaging centre headquarters in Cheltenham. Most staff worked on rotations between mobile units and the service delivered from the main site. All staff attended the main site for training purposes or to attend meetings. This also provided them with the opportunity to be brought up to date with changes at the imaging centre, opportunities to maintain their skills using different equipment located at the imaging centre and to take information back out to the mobile units as required. Other challenges included staffing, recruitment and space, which the senior team were able to clearly discuss and explain how they were managing these.

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.**
- There was a clear set of values for the service, although not all staff were able to recall these. The values for the service included being caring and friendly, professional, innovative, accessible and patient focussed. We spoke with a small number of staff who were not able to remember the values and referred to a quality policy as an aide memoir. We did not notice the values displayed in the imaging centre but noted they were on display in the mobile units. However, throughout the inspection, staff continually demonstrated the values of the organisation, in the way in which they spoke about and engaged with patients.

- There was a future vision for the service. There was a clear focus of maintaining and expanding current high-quality services including further health screening initiatives. The vision was also to continue to contribute and expand on education and participation in ongoing research. Staff spoke with knowledge of the various research programmes the service recruited patients for. There was an enthusiasm to help research projects and the service had exceeded the anticipated number of patient scans. The service was developing a 'school of imaging' and working with a national equipment provider and a local university to develop an academy and to support post-graduate students with learning opportunities. The service was also working with another local university to contribute towards the training programme for radiographer students.
- There was a realistic strategy. We spoke with leaders at various levels and all displayed awareness of and commitment to plans to expand services. This also included the development of their role in research and development programmes to extend education opportunities for their own staff and staff from the local NHS trust. The service worked with a local university to explore opportunities to deliver teaching and facilitate student radiographer placements.
- The service had plans for the replacement of high cost equipment and it was evident that this was reviewed regularly to ensure ongoing services could be maintained.

Culture

- **Staff felt respected, supported and valued. They were focused on the needs of patients receiving care. The service promoted equality and diversity in daily work and provided opportunities for career development. The service had an open culture where patients, their families and staff could raise concerns without fear.**
- Staff at the imaging centre and in the mobile units felt supported, valued and respected. Staff told us they had supportive relationships with their managers and felt comfortable to approach them with any concerns or issues they may have. They felt the environment was supportive and the culture was "friendly", "kind", "open" and "transparent". Staff told us "it is a lovely place to work" and discussed the flexibility to achieve a good work/life balance.

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- The service was centred around the needs of the patients. It was clear from observing care and the way staff interacted with patients that staff were committed to providing high quality care for patients. Staff demonstrated pride in their work and the service they delivered to patients and their service partners.
- Senior leaders were proud of the service they gave to patients and in supporting the NHS to achieve diagnostics for patients. Staff spoke positively about senior leaders and the chief executive. They highlighted good team work and good communication as positive aspects of working for the service.
- Equality and diversity was promoted. It was part of mandatory training, and non-discriminatory practices were part of usual working practice.
- The provider had a whistleblowing policy and a freedom to speak up policy which supported staff to be open and honest. The service had also appointed a freedom to speak up guardian and a deputy for staff to access and raise concerns if required. Staff were aware of who the freedom to speak up guardian was and the name of the deputy for the service. The senior management team told us they were looking to recruit to this post; however, there was no advert out for this at the time of our inspection. Staff told us they would have no concerns in approaching the deputy if required.
- All independent healthcare organisations with NHS contracts worth £200,000 or more are contractually obliged to take part in the Workforce Race Equality Standard (WRES). Providers must collect, report, monitor and publish their WRES data and act where needed to improve their workforce race equality. Although the provider collected this information, senior staff told us publishing it may lead to the identification of individuals due to the service being small. We were told the service was seeking support with how to publish this information whilst maintaining the anonymity of individuals.
- The service had local governance processes, which were achieved through team meetings and local analysis of performance and discussions around other aspects of the service, including incidents and complaints. This fed into processes at a corporate level.
- Performance measures were reported and reviewed. Key performance indicators (KPIs) were maintained for MRI and PET/CT and reviewed at the clinical committee meeting. KPIs were also sent to the commissioners to provide feedback about how the service was performing.
- Governance processes and oversight was achieved through committee meetings and analysis of performance. The clinical governance committee met every six months, with the sub-committees meeting more frequently. There had been a recent change in the sub-committees, with some committees being replaced with others. This was due to some of the meetings duplicating the conversations. The service had service level agreements for the provision of services such as radiation protection advisor, medical physics support and support for nuclear medicine which was provided by an NHS trust.
- Local governance processes were achieved through regional clinical governance meetings, but these were not always held as often as they were meant to be. The meetings were due to be held bi-monthly but had recently slipped to being held every six months. Senior leaders acknowledged this and were planning to get back to holding meetings bi-monthly. We reviewed minutes from the clinical governance committee meetings held in September 2018 and March 2019. These had a rolling agenda which included discussions around adverse reactions, incidents and near misses, new policies, risk, the report from the information governance committee and a review of the risk register. Feedback and actions from performance discussion of local incidents at subcommittee level were fed into the clinical governance committee. We saw evidence of this process through reviewing minutes of meetings. Minutes provided depth and detail of discussion held under each agenda item.
- The clinical committee had been established in May 2019 to replace the senior management committee meeting. Incidents, complaints, KPIs and training were included as items for discussion at this meeting. We

Governance

- **There were governance frameworks to support the delivery of good quality care. However, further work around audit was required to strengthen the governance of the service. 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.**

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reviewed the minutes from the first meeting in May 2019. The minutes contained limited information as to the depth of the discussions held and level of scrutiny around the issues.

- There were radiation protection committee meetings which were held yearly. Issues from this meeting were then fed into the clinical governance meetings. This sub-committee could hold additional meetings if there was a requirement throughout the year. Minutes demonstrated in-depth discussions around each area on the agenda.
- There were processes to monitor the quality and report turnaround times. The quality of images was peer reviewed and quality assured. Deficiencies in images were highlighted to the member of staff for their learning. The service told us that due to demand and capacity, they had been unable to meet their internal target of reviewing 10% of images for each modality on a monthly basis. Due to this, they had hired an external company to carry out this work to ensure targets were met. We reviewed audits which had been carried out on images from X-ray, MRI and MRI on the mobile units. The year to date results for all three areas demonstrated the quality of the images and the reporting was of high quality with no action required.
- There was a comprehensive programme of audit, however from the small sample of audits we reviewed it was not always clear whether there was comprehensive oversight of the audit programme. The service maintained an audit matrix which identified the audits required and the timeframe in which they had to be completed. These included monthly, annual or bi-annual audits consisting of clinical, infection control, information governance, finance and corporate. From the few we reviewed, we found there was not always a formal process to identify the actions required to make the necessary improvements and no record of who was responsible for overseeing these actions were implemented and embedded. There was also no indication when actions had been completed. Following the inspection, the service told us they had completed a review of their audits and had developed action plans where they identified an audit had not met its set target.
- We discussed the service's recent Quality Standard for Imaging (QSI) (formerly ISAS) accreditation. There were two actions required before accreditation could be issued. However, there was no action plan to demonstrate these actions had been achieved, although we were told evidence of completed actions had to be sent to QSI before accreditation could be issued.
- In another example, we discussed an audit which was designed to audit compliance with asking women between the ages of 12 and 55 about their pregnancy status. The audit result showed 85% compliance against an internal target of 100%. There was no action plan to support improvement and no plan to re-audit again until 2020.
- Staff were clear about their roles and understood what they were accountable for. Staff were supported in incident reporting, and championing and implementing local policies and protocols. All clinical staff were professionally accountable for the service and care that was delivered within the unit.
- The hospital had a paediatric management policy, however some responsibilities outlined in the policy were not being followed. The policy stated, 'Cobalt clinical staff had immediate life support (ILS) training for adults and limited training in paediatric resuscitation procedures.' We saw evidence staff had ILS training but no training in paediatric life support.
- Senior leaders sought assurance about the ongoing work carried out by the mobile units. The service had good working relationships with the hosting NHS hospitals, and met with one NHS trust regularly to discuss the work carried out by the service. Each mobile unit provided a daily report of scans carried out which highlighted any issues they had. The service had a designated radiographer who travelled between mobile units to provide support and act as the link between the mobile units and the imaging centre headquarters in Cheltenham.
- The service made sure all staff underwent appropriate checks as required by Schedule three of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014. We reviewed two randomly selected staff files which held all the required information in accordance with legislation.

Managing risks, issues and performance

- **Leaders and teams used systems to manage performance. However, there were limited risks associated with children attending the service on**

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the risk register. We were not assured risks were being regularly reviewed and that actions were being acted on. The service had plans to cope with unexpected events.

- There were systems and processes to identify and manage risks and mitigating actions and a corporate risk register was maintained. Risks were assessed using a risk matrix to identify the level of risk. The risk register identified controls and actions which had been taken to mitigate the risks. Each risk had a named responsible person associated assigned as the 'risk owner' meaning they were responsible for ensuing actions were carried out to lower or remove risks. Risks included operational and information governance risks.
- However, we were not assured risks were being regularly reviewed as we found limited evidence to demonstrate risks were discussed. Risks for the service were reviewed yearly by the board of trustees. We saw evidence of this in meeting minutes from September 2018, although there was no detail behind the discussions and the level of scrutiny regarding the issues. A discussion around risk and the risk register was part of the agenda for the bi-annual clinical governance committee meetings. The minutes from the September 2018 meeting requested staff to 'consider the risks allocated to this committee and remove / add any they feel are appropriate so that this can be reviewed at the next meeting.' We reviewed the minutes from the March 2019 meeting. These state 'no risks were tabled for review at this meeting.' We only found evidence of two other discussions around risks from June 2018, which requested staff to feedback risks which needed to be taken to the board but did not include any documented information to demonstrate a discussion had taken place. We saw one further discussion around new risks in the finance committee meeting minutes from March 2019.
- We had no assurance the due date for mitigating actions had been achieved or implemented. The risk register identified mitigating actions along with a responsible person and a due date for completion. The risk register identified review dates for different risks to be completed by January, September, and December 2018, and March 2019. It was unclear whether these had been completed, whether they were ongoing, how often they were being reviewed or what discussion had been held around each of the actions.
- There were limited entries on the risk register relating to the service provided for children. The only risk identified

was around children's safeguarding. We were not assured risks to children were clearly identified and managed. The risk assessment for children attending PET/CT did not identify the recommendations made by the Royal College of Radiologists: 'Guidelines for the use of PET/CT in children.'

- Risk assessments were completed for various aspects of operational activity across the services. We reviewed some risk assessments which had been completed. The documents contained a good description of the risk and its consequences, along with the control measures and actions taken to mitigate the risks. The risk was also rated and identified a responsible owner and a timeframe for review.
- All eligible staff had had their professional registration checked in the last 12 months. All radiographers were Health and Care Professions Council (HCPC) registered and met the standards to ensure delivery of safe and effective services to patients.
- There was a major incident policy and business continuity plans if the service was to experience a major incident. The policy covered the roles and responsibilities of the staff in major incidents and provided action cards for staff to follow for various major incidents. These included failure of the MRI and PET/CT scanners, a PET radiopharmaceutical major spill, IT system failure, flood, or catastrophic power failure. The business continuity plan provided a risk score for incidents which were likely to affect and impact on the service. An impact analysis had been carried out for each incident, along with the resource requirements for recovery along with associated timeframes.

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.**
- Information was shared between the service and the local NHS trusts they provided services for as part of their contracted work. This enabled images to be reported on by local radiologists and helped to maintain

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the flow of patients through the system. Information from scans could also be reviewed remotely by referrers to give timely advice and interpretation of results to determine onward patient care.

- Staff at the imaging centre and on the mobile units had access to provider policies and resource material through the internal computer system. Staff could locate and access relevant key records electronically. Information was also available at the imaging centre and the mobile units in paper form. This enabled staff to carry out their day to day roles. All staff were familiar with the local rules for the service and how they could access these.
- There were enough computers at the imaging centre and on the mobile units for staff to be able to access the system when they needed to. Staff used radiology specific software systems to ensure relevant people had access to scans. All IT systems were password protected to ensure only authorised persons could gain access. In the mobile scanner units, staff were provided with laptops belonging to the hosting trust to enable them to access relevant information about patients such as when they had arrived. This also allowed staff to communicate directly with referring clinicians by email if they needed specific clarification.
- The service was aware of the requirements of managing a patient's personal information in accordance with relevant legislation and regulations. Electronic patient records were kept secure to prevent unauthorised access to data. Authorised staff demonstrated they could be easily accessed when required.

Engagement

- **Leaders and staff actively and openly engaged with patients, staff, the public and local organisations to plan and manage services, but there was not always evidence to demonstrate recommendations had been acted on. They collaborated with partner organisations to help improve services for patients.**
- Patients' views and experiences were gathered and used to shape and improve the services and culture. Following their visit to the unit, patients were sent a satisfaction questionnaire. In April 2019, out of 1,172 questionnaires sent out, 107 patients responded (9.1%). Data showed 84.8% of respondents rated the service as very good, 9.4% rated it as good and 5.5% felt it was neither good nor poor. Only 0.3% of patients rated the unit as poor. In May 2019, out of 1,227 questionnaires

sent out, 280 (22.8%) were returned. The general analysis of the survey demonstrated 85.6% of respondents rated the unit as very good, 10.2% rated it as good and 3.5% felt it was neither good nor poor. Less than 1% of respondents rated the unit as poor or very poor.

- There was regular engagement with commissioners to understand the services they required and how they could be improved. This produced an effective pathway for patients. The service had a good relationship with the host hospital NHS trusts and staff told us seniors from the trusts were supportive and reported good lines of communication.
- The service received feedback from staff. A staff survey was carried out on a yearly basis, with 62 staff completing the survey in 2018. The survey identified a list of recommendations, including clarification about the line management structure, action to improve health and wellbeing, ensuring appraisals were carried out in a timely way, improving communication between management and staff and creating more career opportunities for staff. The recommendations had a date next to them indicating when they needed to be completed, however there was no formal documentation or audit trail to show that the actions had been implemented. Following the inspection we were sent additional evidence to demonstrate that the recommendations from the survey had been acted on and implemented.

Learning, continuous improvement and innovation

- **All staff were committed to continually learning and improving services. They had a good understanding of quality improvement methods and the skills to use them. Leaders encouraged innovation and participation in research.**
- The service was committed to improving services by promoting training, research and innovation. The service had been part of 33 different national and international research studies. These included an oncology project such as lymphoma, oesophageal cancer and myeloma. The service funded two research nurses to help research projects into diagnosis of dementia using PET/CT scans and a research fellow working at a local university to develop further research.
- In 2017, the service purchased a cone beam CT (CBCT) scanner. The clinical imaging site in Cheltenham was the

Diagnostic imaging

first clinical site in the world for this new system. The scanner enabled patients to have their joints scanned in a weightbearing position, enhancing optimal diagnosis for patients.

Outstanding practice and areas for improvement

Outstanding practice

- Staff worked closely with the referring NHS trust to carry out additional scans when significant findings were identified. This prevented patients from having to return to the service for additional scans which could lead to a delay in accessing treatment.
- The provider offered 800 free scans to support the local NHS trust to meet demand and ensure timely diagnostic scans for patients.
- Cobalt Health provided facilities free of charge for the local NHS trust to carry out 'one stop' clinic for patients referred for musculoskeletal complaints. Patients could receive scans and advice or treatment without the need for further waiting to attend for scans.
- Cobalt Health provided facilities free of charge to accommodate a breast screening service provided by the local NHS trust to help them meet demand.

Areas for improvement

Action the provider **MUST** take to improve

- Ensure Patient Group Directions have the necessary authorisation to enable approved use.
- Ensure there is an active Patient Group Direction for the use of saline when giving medicines or radioactive tracers intravenously.

Action the provider **SHOULD** take to improve

- Consider ways to demonstrate compliance with the daily cleaning of scanning rooms and keep these up to date.
- Review risk assessments regularly to make sure they remain in line with national guidance.
- Take account of all relevant sources of advice in assessing risks and managing paediatrics safely.
- Document the outcomes of risk assessments which are carried out on an individual patient basis, including those around mental capacity, to ensure there is an audit trail with the rationale behind the decisions taken.
- Consider documenting when patients have received post-care information and patient presentation on leaving the unit to ensure a clear record of the care provided is in the patient record.
- Look at ways to provide assurance that recommendations from audits have been acted on and implemented.
- Monitor compliance with all aspects of policies.
- Improve the quality of meeting minutes to provide detail around the discussions held.
- Identify, mitigate, review and discuss all risks associated with the service and maintain records of each activity.
- Act on recommendations from the staff survey.

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 Treatment of disease, disorder or injury	<p>Regulation 12 HSCA (RA) Regulations 2014 Safe care and treatment</p> <p>Regulation 12(1) – Care and treatment must be provided in a safe way for service users.</p> <p>Patient group directions (PGDs) were not used in accordance with The Human Medicine Regulations 2012 regulation.</p> <p>There were no PGDs for the use of saline, which meant these were given without a prescription or authorisation.</p>