Park View Medical Centre

Quality Report

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

Ratings

Overall rating for this location	**Inadequate**
Are services safe?	**Inadequate**
Are services effective?	**Not sufficient evidence to rate**
Are services caring?	**Requires improvement**
Are services responsive?	**Requires improvement**
Are services well-led?	**Inadequate**

Overall summary

Park View Medical Centre is operated by Mrs Susan Elizabeth Appleton. The service has one standalone X-ray facility providing diagnostic imaging service for adult patients. The provider is also the registered manager for the service and the single radiographer operating the service.

We inspected this service using our comprehensive inspection methodology. We carried out a short-notice announced inspection on 20 February 2019.

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

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

Summary of findings

Our rating of this service was **Inadequate** overall.

We found areas of practice that were inadequate:

- The service did not have agreed protocols of imaging for each anatomical area with the referring consultant, and the radiographer was not aware that she was responsible for justification of every incidence of patient exposure to radiation and for each decision whether, and how, to X-ray.
- There was no record of any provision by the referrer of relevant patient histories or clinical information on which to base a decision, and there was no record of any clinical question to be answered by the X-ray image.
- The radiographer did not carry out a 'Three Points of ID' check or use the Society of Radiographers (SoR) 'Pause and Check' protocol before the X-ray procedure.
- The radiographer did not record the Dose Area Product (DAP) following the X-ray procedure.
- The service did not provide mandatory training in key skills to staff.
- The service did not carry out any hand-hygiene or other infection prevention and control audits, and we observed poor practice in hand hygiene during the inspection.
- The provider did not understand what might constitute a serious or clinical incident. There was no information available for staff about their responsibilities to raise concerns, to record safety incidents, concerns or near misses, and to report these internally and externally. Nor was there any information about how to investigate or learn from any incident.
- Staff did not complete risk assessments for patients. The service did not have systems to identify risks and to plan to eliminate or reduce them or to cope with both the expected and unexpected. The service's risk management policy lacked expected detail.
- There were no systems of accountability within the service; the radiographer did not keep any records of her work that could be audited or monitored to provide assurance in respect of safety or outcomes for patients.
- Staff employed by the service had not undergone any checks to ensure the employment of fit and proper persons.
- There was no programme of clinical or internal audit to monitor quality or operational processes, and there were no systems to identify where action should be taken. There was no monitoring or reporting of service performance measures.
- There was no provision to patients of any statement that included terms and conditions of the service being provided.
- There were no arrangements to ensure the availability, integrity or confidentiality of identifiable data or records; medical records kept were insufficient and were not held securely.
- The provider did not have any duty of candour policy or any other written processes to ensure that the service met this duty.
- The radiographer had not undertaken any ongoing training or professional development in the radiography field.
- There was no formal vision or strategy document for the service.
- There were no mechanisms for providing staff with opportunities for development.

We found areas of practice that required improvement:

- The radiographer did not introduce herself or others to patients, nor did she ask patients whether they were comfortable with others being in the room during X-ray procedures.
- Staff did not fully involve patients and those close to them in decisions about their care and treatment; the radiographer did not discuss alternative imaging modalities with patients or encourage them to be part of the decision-making process.
- Staff were not aware of the potential need to seek accessible ways to communicate with people.
- There was no evidence of promotion of equality and diversity within or beyond the service.
- The service did not fully plan and provide services in a way that met the needs of local people. Access to parts of the service was difficult for anyone whose mobility was restricted, and there were no adjustments to the service to allow people with a disability to access and use services. The service did not use any schemes to support those with dementia, learning disabilities, autism or other additional needs.

Summary of findings

- There were no adjustments to the service to ensure that it took account of the needs of different people, including those with protected characteristics under the Equality Act 2010 and those in vulnerable circumstances.

However, we found good practice in relation to:

- Staff we spoke with enjoyed working for the service and had no concerns about culture. There was a friendly and welcoming atmosphere amongst staff, and they interacted with people in a pleasant manner.
- Feedback from patients confirmed that staff treated them well and with kindness. Patients were very complimentary about the service.

Following this inspection, we told the provider that it must take some actions to comply with the regulations. We suspended regulated activity at the location following our inspection, and we gave the provider 35 days to address the breaches and concerns that we raised. This notice of urgent suspension of registration was given because we believed that a person would or might be exposed to risk of harm if we did not take this action. Details are at the end of the report.

Ellen Armistead

Deputy Chief Inspector of Hospitals (North)

Summary of findings

Our judgements about each of the main services

Service	Rating	Summary of each main service
Diagnostic imaging	Inadequate 	The service provided plain film X-rays for adult patients on referral from an independent orthopaedic consultant during his weekly clinics at the location. We rated the service as inadequate, because there were failings in safety, responsiveness and leadership.

Summary of findings

Contents

Inadequate

Park View Medical Centre

Services we looked at:
Diagnostic imaging.

Summary of this inspection

Background to Park View Medical Centre

Park View Medical Centre is operated by Mrs Susan Elizabeth Appleton. The service opened in the 1990s and was registered with CQC in May 2011. It is a private facility in Middlesbrough, Cleveland, and primarily serves the communities of the North East of England. The service offers private rooms for hire for consultations, counselling sessions, and complementary therapies, along with support services to the doctors and other healthcare professionals who use those rooms. Amongst the support services offered is the provision of plain film X-rays on request; the service is therefore registered with CQC to provide diagnostic and screening procedures.

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

We have inspected this service once previously, in 2013, when it was found to be meeting each of the criteria then assessed.

Our inspection team

A CQC inspector led this inspection, with remote support from a special advisor in diagnostic imaging services. The inspection team was overseen by Sarah Dronsfield, Head of Hospital Inspection.

Information about Park View Medical Centre

The service is registered to provide the following regulated activities at this location:

- Diagnostic and screening procedures.

There is a standalone X-ray room in the building, housing one X-ray machine, where the provider carries out around three X-ray procedures per week.

The service is owned and run by its registered manager, Mrs Susan Elizabeth Appleton, who is a diagnostic radiographer. She works part time at the service and employs three part-time receptionists and a cleaner.

At the time of our inspection, referrals to the service were made by an orthopaedic consultant who held clinics on one morning each week at the location in a private, self-employed capacity. The provider had not taken referrals from any other source in the 12 months prior to our inspection.

Patients who had appointments to see the orthopaedic consultant reported to the main reception and were shown to the waiting room, which was a shared room for all services using the building. From there, the consultant collected patients to take them to his consulting room. When he required an X-ray for a patient, he alerted the radiographer, who took the patient to the X-ray room to carry out the procedure. The patient then waited in the X-ray room whilst the film was developed, and then the radiographer took the patient back to the consultant's room. These rooms were all on the ground floor.

During our inspection, we visited the registered address. We spoke with the registered manager/radiographer and two receptionists. We spoke with, and observed the care given to, two patients and one relative who visited the clinic that day. We looked at all available patient records from the 12 months prior to our inspection, including examining a sample of seven sets of those in detail (although they were very limited), and we reviewed other information about, and provided by, the service.

There were no ongoing special reviews or investigations of Park View Medical Centre by CQC at any time during the 12 months prior to this inspection. This was the

Summary of this inspection

service's second inspection since registration with CQC. The first inspection was undertaken in January 2013, and the provider was found to be meeting all standards that were measured at that time.

Activity (January 2018 to January 2019)

- In the reporting period from January 2018 to January 2019, there were approximately 125 episodes of care within the X-ray service at Park View Medical Centre. However, the exact number could not be established during our inspection, due to a lack of medical records. All episodes of care were privately funded.

Track record on safety:

In the 12 months prior to the inspection there had been

- Zero never events
- Zero deaths
- Zero serious incidents
- Zero clinical incidents
- Zero incidences of healthcare acquired methicillin-resistant staphylococcus aureus (MRSA)
- Zero incidences of healthcare acquired methicillin-sensitive staphylococcus aureus (MSSA)
- Zero incidences of healthcare acquired clostridium difficile (C.diff)
- Zero incidences of healthcare acquired Escherichia coli (E-Coli)
- Zero complaints.

Services provided at the location under service level agreement:

- Non-clinical waste removal
- Laundry.

The private consulting rooms, counselling sessions, and complementary therapies carried out by other providers at this location were not regulated by CQC and so were not inspected.

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?

Inadequate

Our rating of safe was **Inadequate** because:

- The service did not have agreed protocols of imaging for each anatomical area with the referring consultant, and the radiographer was not aware that she was responsible for justification of every incidence of patient exposure to radiation and for each decision whether, and how, to X-ray.
- There was no record of any provision by the referrer of relevant patient histories or clinical information, nor was there any information recorded about the clinical question to be answered by the X-ray image.
- The radiographer did not carry out a 'Three Points of ID' check or use the Society of Radiographers (SoR) 'Pause and Check' protocol or similar before the X-ray procedure.
- The radiographer did not record the Dose Area Product (DAP) following the X-ray procedure.
- Staff did not keep detailed records of patients' care and treatment, and records that were held were not kept securely.
- The service did not provide mandatory training in key skills to staff.
- The service did not carry out any hand-hygiene or other infection prevention and control audits, and we observed poor practice in hand hygiene during the inspection.
- The provider did not understand what might constitute a serious or clinical incident.
- There was no information available for staff about their responsibilities to raise concerns, to record safety incidents, concerns or near misses, and to report these internally and externally. Nor was there any information about how to investigate or learn from any incident.
- The premises were not suitable for anyone whose mobility was restricted.
- Staff did not complete risk assessments for patients.

However:

- The service had suitable equipment and looked after it well.
- The radiographer used personal protective equipment when needed, and provided lead protection where appropriate for patients.

Are services effective?

Not sufficient evidence to rate

We do not currently rate the effectiveness of diagnostic services.

Summary of this inspection

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

- The radiographer did not follow Society of Radiographers (SoR) clinical guidelines, in that she did not explain risk, offer alterative imaging modalities where appropriate, or keep any record of patient consent.
- The radiographer did not carry out an holistic assessment of people's physical, mental health and social needs, or use clinical histories to support the decision to X-ray.
- The service did not carry out any clinical audits or audits of diagnostic reference levels (DRLs) used.
- The service did not collect information about the outcomes of people's care and treatment.
- The service did not ensure that staff were competent for their roles; the radiographer had not undertaken any up-to-date professional training.
- There was no evidence that staff had trained in line with Control of Substances Hazardous to Health Regulations 2002 (COSHH).

Are services caring?

Requires improvement

Our rating of caring was **Requires improvement** because:

- The radiographer did not introduce herself or others to patients, nor did she ask patients whether they were comfortable with others being in the room during X-ray procedures.
- Staff did not fully involve patients and those close to them in decisions about their care and treatment; the radiographer did not discuss alternative imaging modalities with patients or encourage them to be part of the decision-making process.
- Staff were not aware of the potential need to seek accessible ways to communicate with people.

However:

- During our inspection we observed that staff interacted with people in a pleasant and friendly way.
- Feedback from patients confirmed that staff treated them well and with kindness.

Are services responsive?

Requires improvement

Our rating of responsive was **Requires improvement** because:

- The service did not fully plan and provide services in a way that met the needs of local people. Access to and from the consulting rooms, waiting room and toilet was very difficult for anyone whose mobility was restricted.

Summary of this inspection

- There were no adjustments to the service to allow people with a disability to access and use services on an equal basis to others; there were no facilities for users of wheelchairs or for others with restricted mobility.
- Information for patients was not provided in any accessible formats, such as braille or large print.
- The service did not use any schemes to support those with dementia, learning disabilities, autism or other additional needs.
- There were no adjustments to the service to ensure that it took account of the needs of different people, including those with protected characteristics under the Equality Act and those in vulnerable circumstances.
- The service did not provide any information in other languages.

However:

- The radiographer was always on site during the referring consultant's clinics and carried out X-rays immediately; there was no waiting for patients, once referred.
- The service had an appropriate complaints policy, which was displayed in the X-ray room.
- There had been no complaints in the 12 months prior to our inspection.

Are services well-led?

Inadequate 

Our rating of well-led was **Inadequate** because:

- There were no systems of accountability within the service; the provider did not recognise that she was responsible for deciding whether and how to X-ray a patient, and she did not keep any records of her work that could be audited or monitored to provide assurance in respect of safety or effectiveness.
- The provider's working relationship with the referring consultant was not formalised or subject to any written agreements or protocols.
- Staff employed by the service had not undergone any checks to ensure the employment of fit and proper persons.
- The service did not have systems to identify risks and plan to eliminate or reduce them or to cope with both the expected and unexpected.
- There was no programme of clinical or internal audit to monitor quality or operational processes, and there were no systems to identify where action should be taken.
- The service's risk management policy lacked expected detail, and the service did not have a system to manage risks.

Summary of this inspection

- There was no monitoring or reporting of service performance measures.
- There was no provision to patients of any statement that included terms and conditions of the service being provided.
- There were no arrangements to ensure the availability, integrity or confidentiality of identifiable data or records; medical records kept were insufficient and were not held securely.
- The radiographer had not undertaken any ongoing training or professional development in the radiography field.
- There was no formal vision or strategy document for the service.
- There were no mechanisms for providing staff with opportunities for development.
- There was no evidence of promotion of equality and diversity within or beyond the service.
- The provider did not have any duty of candour policy or any other written processes to ensure that the service met this duty. Staff had not undertaken any training in duty of candour.

However:

- Reception staff described the registered manager as visible and approachable.
- Staff we spoke with enjoyed working for the service and had no concerns about culture. There was a friendly and welcoming atmosphere amongst staff.
- The provider's incident-reporting policy contained information for staff about what to do in the event of a radiation incident.

Detailed findings from this inspection

Overview of ratings

Our ratings for this location are:

	Safe	Effective	Caring	Responsive	Well-led	Overall
Diagnostic imaging	Inadequate	Not rated	Requires improvement	Requires improvement	Inadequate	Inadequate
Overall	Inadequate	Not rated	Requires improvement	Requires improvement	Inadequate	Inadequate

Inadequate

Diagnostic imaging

Safe	Inadequate
Effective	Not sufficient evidence to rate
Caring	Requires improvement
Responsive	Requires improvement
Well-led	Inadequate

Are diagnostic imaging services safe?

Inadequate

We rated safe as **inadequate.**

Mandatory training

- The service did not provide mandatory training in key skills to all staff. The provider confirmed that there was no list of mandatory training for staff other than the radiographer.
- The radiographer was qualified in diagnostic radiography and was registered with the Health and Care Professions Council (HCPC) as a diagnostic radiographer.
- There was no evidence that the radiographer had undertaken any further training in Ionising Radiation (Medical Exposure) Regulations IR(ME)R, radiation risks, or use of radiation since her qualification over 40 years ago.
- The radiographer had undertaken online training in fire safety, in emergency first aid at work, and in safeguarding in the twelve months prior to our inspection.

Safeguarding

- We requested evidence that staff working at the service had been subject to a formal Disclosure & Barring Service (DBS) check, but no evidence was provided to us.
- The radiographer told us that she was trained to level 2 in safeguarding adults. She understood how to report signs of abuse and kept appropriate, up-to-date contact details should she need to raise a concern with the local authority. She told us that she had never had any cause to raise a safeguarding concern whilst running the service.
- There was no evidence that other staff had received any training in safety systems, processes and practices. Staff had not training on how to recognise and report abuse.
- The service had a safeguarding policy covering children and vulnerable adults. The policy highlighted the responsibilities of all those who come into contact with children to report actual or suspected abuse and of healthcare professionals to be alert to abuse of vulnerable adults and be proactive in raising concerns. It did not name the safeguarding lead, but it outlined the process for raising concerns with the local authority or police. The policy contained up-to-date contact details for the local authority safeguarding team.
- During our inspection, the radiographer told us that she would always check a patient's identity before carrying out an X-ray, and we observed that she asked patients to confirm their names and the area to be X-rayed.
- There was no safeguarding information on display at the location.

Cleanliness, infection control and hygiene

- During the inspection we found the premises and equipment to be visibly clean and in good working order. The X-ray room appeared to be clean, tidy, and free from clutter.
- There were hand-washing facilities and alcohol gels available within the X-ray room.
- The service used single-use supplies where possible, and the X-ray table was covered with disposable paper roll, which was changed between each patient usage.

Inadequate

Diagnostic imaging

- The radiographer told us that she was the service lead for infection prevention and control (IPC). There was an IPC policy which outlined the essential principles of IPC, general responsibilities, and responsibilities of the service IPC lead.
- During our inspection the radiographer did not decontaminate her hands before or after helping patients onto the X-ray table or handling gowns used by patients.
- The service policy included the IPC lead's responsibility to undertake audits of infection control procedures and cleanliness. However, the service lead did not carry out any hand-hygiene or other IPC audits.
- The service used a contractor to clean patient gowns. The provider told us that she cleaned the X-ray equipment herself and employed a part-time cleaner to clean the premises each day.

Environment and equipment

- The service was housed in a large, detached building with private parking for staff and patients. There were a reception room, an X-ray room, a darkroom, a waiting room, consulting rooms and a toilet on the ground floor, all of which were used by the service.
- The premises were not entirely suitable for the service. There were several steps between the front part of the ground floor, which housed the reception, an office and the X-ray room, and the rest of that floor. This meant that access to and from the consulting rooms, waiting room and toilet was difficult for anyone whose mobility was restricted. During our inspection, two of the patients who used the service were there to have knee X-rays taken, and both of these patients experienced some difficulties when descending and ascending these steps.
- The X-ray room was large enough to accommodate the X-ray equipment and provide sufficient space for staff to work safely.
- A changing cubicle was accessed via the X-ray room, meaning that patient's privacy and dignity were maintained whilst changing before and after the X-ray procedure.
- The service had suitable equipment and looked after it well. The X-ray unit was registered with the Health & Safety Executive (HSE) under the Ionising Radiations Regulations 2017 (IRR17). We saw evidence that the unit had been serviced in July 2018 and found to conform fully to IRR17 approved codes of practice and guidance notes.
- We saw evidence that the service maintained and tested its portable electrical equipment regularly, in line with HSE guidance; the equipment bore stickers showing the most recent and next due test dates.
- The X-ray room was clearly signposted and radiation warning information was displayed. There were no working warning lights, but the radiographer told us that she always locked the door when an X-ray was being taken, and we observed her doing so during our inspection.
- The radiographer used personal protective equipment when needed, and provided lead protection where appropriate for patients.
- We asked for evidence that lead aprons and lead screens were checked regularly for damage, but this was not provided to us.
- There was no evidence that the provider undertook assessments and reviews of the service's activities under the Control of Substances Hazardous to Health Regulations 2002 (COSHH).
- The radiographer wore a personal dosimeter to measure the amount of radiation received. Dose information was stored by the service's contracted monitoring service, which produced online reports of radiation exposure.

Assessing and responding to patient risk

- Staff did not complete a risk assessment for each patient.
- We requested evidence from the provider that she had agreed protocols of imaging for each anatomical area with the referring consultant, but she did not respond to our request.
- There were no records of referrals to the service. The referring consultant made a verbal request to the radiographer, who was not aware that, as practitioner, she was responsible for justification of every incidence of patient exposure to radiation and for each decision whether, and how, to X-ray. She described herself as taking instruction from the referring consultant. There was no record of any provision by the consultant of relevant patient histories or clinical information, nor was there any information recorded about the clinical question to be answered by the X-ray image.

Inadequate

Diagnostic imaging

- During our inspection we observed that the radiographer asked patients to confirm their names and the area to be X-rayed before carrying out the procedure. However, she did not carry out a 'Three Points of ID' check or use the Society of Radiographers (SoR) 'Pause and Check' protocol or similar.
- Radiation risks to patients were not managed in line with guidance from the International Atomic Energy Agency (IAEA) guidance 'Radiation Protection and Safety in Medical Uses of Ionizing Radiation': The radiographer used her own set of diagnostic reference levels (DRLs) to determine exposure levels for X-rays, displaying these on the wall in the X-ray room. She told us that she would deviate from these standards only when she judged that a greater or lesser dose was required, for example, when a patient was much smaller or larger than average. She understood that the dose area product (DAP) must be kept a low as reasonably practicable (ALARP).
- The radiographer told us that she did not usually record the DAP for each patient. When we raised this concern with her during the inspection she told us that she would begin to do so immediately.
- The service used the same contractor as both radiation protection advisor (RPA) and medical physics expert (MPE). He was contactable by telephone or email when the radiographer required radiation advice. The provider told us that the RPA visited the service once in every two to three years to carry out checks or assess any new equipment.
- The service did not have a named radiation protection supervisor (RPS), but used a regional NHS trust's Imaging Physics & Radiation Safety department for RPS support. However, the contact details for that department given to us by the provider were incorrect, and the provider did not respond to a subsequent request for the correct details. The provider told us that the senior radiologist from that service would visit weekly to report on any chest X-rays that she took, although this now happened very rarely.
- The X-ray room was clearly signposted and radiation warning information was displayed both inside and outside of the room, but there was no similar information in the waiting room.
- There were signs within the X-ray room and the changing room asking patients to let the radiographer know if they might be pregnant, and the radiographer told us that she would always ask any woman of child-bearing age whether she could be pregnant before carrying out an X-ray. However, the service did not keep any record of such checks.
- The local rules (under IRR) and procedures (under IR(ME)R) to protect staff and patients from ionising radiation were displayed on the wall of the X-ray room.
- There were no written pathways or processes for the assessment of people using the service who were clinically unwell or whose health was deteriorating, nor were there any for medical emergencies or challenging behaviour. The radiographer told us that the referring consultant would not book appointments for patients with this level of need at the service; if a medical or other emergency were to occur she would make a 999 call.

Radiographer and medical staffing

- The service was run by the provider, who was a diagnostic radiographer and worked part-time. She was supported by three part-time receptionists, one of whom would sometimes develop X-ray films. No other staff were involved in the X-ray procedure.
- The radiographer told us that she could contact a radiologist from a regional NHS trust for advice.

Records

- Staff did not keep detailed records of patients' care and treatment. This was not in line with IR(ME)R, which requires the practitioner to retain a record of the clinical details and clinical question to be answered when carrying out an X-ray. When the referring consultant required an X-ray for a patient, he made a verbal request to the radiographer and gave her the patient's medical record file. The radiographer photocopied the letter to the consultant from the GP/other referrer, and she made a note on the photocopy of the area that she had X-rayed. She then returned the file to the consultant. The photocopy, which usually bore the patient's name, contact details and date of birth, was therefore the only medical record kept by the service. This meant that there would not be any information available to the service, or any other provider, for any subsequent provision of care or treatment to the patient.

Inadequate

Diagnostic imaging

- Records were not kept securely. They were held in a box file on a shelf in the reception room. Although the provider told us that this room was always locked when staff were not present, during our inspection we found the room unlocked yet unoccupied.

Incidents

- In the 12 months prior to our inspection there had been no report of any never event. A never event is a serious incident that is wholly preventable as guidance, or safety recommendations providing strong, systemic protective barriers, are available at a national level and should have been implemented by all providers. The event has the potential to cause serious patient harm or death, has occurred in the past, and is easily recognisable and clearly defined.
- In the 12 months prior to our inspection there had been no report of any death, serious incident, or clinical incident.
- In the 12 months prior to our inspection there had been no report of any incidence of healthcare-acquired meticillin-resistant staphylococcus aureus (MRSA), meticillin-sensitive staphylococcus aureus (MSSA), clostridium difficile (C.diff) or Escherichia coli (E-Coli).
- The provider told us that the service had an incident-reporting policy. However, on examination, this applied only to incidents in which a patient was exposed to ionising radiation much greater than intended and only when this was not due to an equipment malfunction or defect. The provider did not seem to understand what else might constitute a serious or clinical incident.
- The incident-reporting policy explained to staff that any exposure to ionising radiation that was much greater than intended must be reported to CQC and included a link to further information on the CQC website. However, there was no other information available for staff about their responsibilities to raise concerns, to record safety incidents, concerns or near misses, and to report these internally and externally. Nor was there any information about how to investigate or learn from any incident.
- There was no information for staff about duty of candour regulations.

Are diagnostic imaging services effective?

Not sufficient evidence to rate

We do not currently rate effectiveness for diagnostic services**.**

Evidence-based care and treatment

- The service did not always provide care and treatment on the basis of national guidance. Staff did not carry out an holistic assessment of people's physical, mental health and social needs; the radiographer simply took instruction from the referring consultant about which anatomical area to X-ray, which was not in line with Ionising Radiation (Medical Exposure) Regulations (IR[ME]R).
- The radiographer used her own set of diagnostic reference levels (DRLs) to determine exposure levels for X-rays, displaying these on the wall in the X-ray room. We asked for evidence that these DLRs were based on the National Diagnostic Reference Levels (NDRLs) for the UK published by Public Health England (PHE), but the provider did not respond to our request.
- The provider told us that she did not carry out any audits of DRLs used.
- The provider did not carry out any clinical audits.

Nutrition and hydration

- The provider told us that the service offered hot and cold drinks and biscuits to patients who were waiting.

Pain relief

- The provider told us that the service did not assess or manage patient's pain, as the referring consultant would not make appointments at this service for patients who might require pain relief.

Patient outcomes

- The service did not collect information about the outcomes of people's care and treatment.
- The provider did not participate in the Imaging Services Accreditation Scheme (ISAS).
- The service did not review the effectiveness of care and treatment through local audit or national audit.

Competent staff

- The service did not ensure that staff were competent for their roles. The radiographer was qualified in diagnostic

radiography and was registered with the Health & Care Professions Council (HCPC) as a diagnostic radiographer. However, there was no evidence that she had undertaken any further training in IR(ME)R, radiation risks, or use of radiation since her qualification over 40 years ago.

- One of the receptionists regularly developed plain film images for the radiographer. However, there was no evidence that she had trained in line with Control of Substances Hazardous to Health Regulations 2002 (COSHH).
- There were no arrangements for one-to-one meetings, appraisals, or coaching or mentoring of staff in the service.
- The radiographer did not seek opportunities to develop professionally, as she was considering retirement at the time of our inspection.

Multidisciplinary working

- The service did not make use of any previous images of the same persons requiring the test, because the radiographer simply took instruction from the referring consultant and did not follow the process of justification to carry out exposure to radiation.

Consent, Mental Capacity Act and Deprivation of Liberty Safeguards

- The radiographer told us that she sought verbal consent to the X-ray procedure from each patient. However, she did not follow Society of Radiographers (SoR) clinical guidelines, in that she did not explain risk, offer alternative imaging modalities where appropriate, or keep any record of patient consent.
- The radiographer told us that she did not need to understand or use the relevant consent and decision-making requirements of the Mental Capacity Act 2005, because any issues relating to mental capacity would be addressed by the referring consultant.

Are diagnostic imaging services caring?

Requires improvement

We rated caring as **requires improvement.**

Compassionate care

- During our inspection we observed that staff interacted with people who used the service and those close to them in a friendly and pleasant way. The patients and relative we spoke with described staff as kind and friendly. However, we observed that the radiographer did not introduce herself or others to patients, nor did she ask patients whether they were comfortable with others being in the room during X-ray procedures.
- Patients were able to speak to the receptionist without being overheard by requesting that the door to the reception room be closed.
- The radiographer told us that one of the receptionists would act as chaperone for any patient who requested this. As both receptionists were female, the referring consultant would fulfil the role when a male chaperone was required.
- We reviewed seven patient survey questionnaires that had been returned to the provider. Feedback from patients confirmed that staff treated them well and with kindness.

Emotional support

- The service did not provide information about how to find support services; the provider told us that this would be covered by the referring consultant.
- The service did not provide people who used services with information leaflets or other written information to explain their condition and treatment plan, or what do to do in the event they had any concern once discharged; again, the provider told us that this would be covered by the referring consultant.

Understanding and involvement of patients and those close to them

- Staff did not fully involve patients and those close to them in decisions about their care and treatment. The radiographer did not discuss alternative imaging modalities with patients or encourage them to be part of the decision-making process. However, she did check the area to be X-rayed before carrying out the procedure, and she explained why the patient needed to change position to take an image from a different angle. She helped patients onto the X-ray table and to move once on the table, if need be.

Inadequate

Diagnostic imaging

- The provider told us that the referring consultant did not arrange appointments for people with protected equality characteristics or other different needs at this service, so there was no need for staff to seek accessible ways to communicate with people.
- The patients and relative we spoke with told us that staff welcomed them and those close to them. Patients understood the process and that they would receive their X-ray results immediately on return to the consultant's room.

Are diagnostic imaging services responsive?

Requires improvement

We rated responsive as **requires improvement.**

Service delivery to meet the needs of local people

- The service did not fully plan and provide services in a way that met the needs of local people. Although, X-ray room was spacious and easily accessible from the front door and the reception, there were several steps between the front part of the ground floor, which housed the reception, an office and the X-ray room, and the rest of that floor. This meant that access to and from the consulting rooms, waiting room, and toilet was difficult for anyone whose mobility was restricted.
- The provider told us that disabled people and people with restricted mobility were not offered appointments at this location by the referring consultant but they could be accommodated if need be by waiting in the entrance hallway, which was spacious and contained a chair, and having the consultant come to the office in the front part of the building to see them. However, during our inspection, two of the patients who used the service were there to have knee X-rays taken, and neither had been offered these alternative arrangements, despite experiencing some difficulties when descending and ascending the steps.
- The environment was comfortable, with sufficient seating in the waiting room and toilets for patients.
- There were magazines available in the waiting room, and the provider told us that she offered patients hot and cold drinks and biscuits.

Meeting people's individual needs

- The service did not take account of patients' individual needs. There were no adjustments to the service to allow people with a disability to access and use services on an equal basis to others; there were no facilities for users of wheelchairs or for others with restricted mobility.
- The provider told us that information for patients was not provided in any accessible formats, such as braille or large print.
- The service did not use any schemes to support those with dementia, learning disabilities, autism or other additional needs. Again, the provider told us that there was no demand for these, as the referring consultant did not book appointments at the service for those who might require additional support.
- There were no adjustments to the service to ensure that it took account of the needs of different people, including those with protected characteristics under the Equality Act 2010 and those in vulnerable circumstances.
- The service did not provide any information in other languages. The provider told us that there was very little need for this in the local population.
- The provider told us that she had access to a language translation service but had not needed to use it.

Access and flow

- The referring consultant arranged his weekly clinic in line with the radiographer's availability, so she was always on site during clinics and carried out X-rays immediately upon referral from him. There was therefore no waiting for patients, once referred.
- The X-ray film was developed whilst the patient waited in the X-ray room. Once the radiographer had checked that the image was usable, she escorted the patient back to the waiting room or consultant's room.

Learning from complaints and concerns

- The service had a complaints policy, which outlined how any complaint would be investigated, responded to and, if appropriate, apologised for and described how the service would learn from complaints and patient feedback.
- The complaints policy was displayed in the X-ray room.
- Staff we spoke with understood the complaints policy and knew how to advise any patients who raised a concern with them.

- There had been no complaints in the 12 months prior to our inspection.

Are diagnostic imaging services well-led?

Inadequate

We rated well-led as **inadequate.**

Leadership

- The service was owned and run by the registered manager, who was also the head of clinical service as the only radiographer. She was therefore the individual with authority within the service and was responsible for the overall quality and safety of care. She was a qualified diagnostic radiographer, was registered with the Health & Care Professions Council (HCPC), and had over 40 years of experience in her role.
- There was no evidence that the registered manager had undertaken any ongoing training or professional development in the radiography field to develop her skills and knowledge and stay up-to-date with best practice.
- The provider recognised that the service she provided was becoming outdated and so was not sustainable in its current form. At the time of our inspection she was considering retirement, which would lead to closure of the radiography service at the location. Therefore, there was no leadership strategy, development programme, or succession planning within the service.
- The registered manager was on site part time, and the reception staff described her as visible and approachable.

Vision and strategy

- There was no formal vision or strategy document for the service. The purpose of the service was described on its website as the provision of first-class, private, consulting rooms to rent, with the aim of facilitating private access to local consultants, and any associated diagnostic services, within the North East of England.

Culture

- Staff we spoke with enjoyed working for the service and had no concerns about culture. There was a friendly and welcoming atmosphere amongst staff.
- There were no mechanisms for providing staff with opportunities for development; there was no appraisal system or plan for career development.
- There was no evidence of promotion of equality and diversity within or beyond the service.
- The provider did not have any duty of candour policy or any other written processes to ensure that the service met this duty. Staff had not undertaken any training in duty of candour.

Governance

- There were no systems of accountability within the service. The provider did not recognise that she was responsible for deciding whether and how to X-ray a patient. She did not keep any records of her work that could be audited or monitored to provide assurance in respect of safety or effectiveness.
- The provider's working relationship with the referring consultant was not formalised or subject to any written agreements or protocols.
- Medical physics expertise was sought through a third-party provider, who was available by telephone and email and visited the service once every two to three years.
- Staff employed by the service had not undergone any checks to ensure the employment of fit and proper persons; the three receptionists employed by the service had worked for the service since it opened. They were known to the provider at that time and so had not undergone any formal recruitment process. The cleaner was retained on an informal basis.

Managing risks, issues and performance

- The service did not have systems to identify risks and plan to eliminate or reduce them or to cope with both the expected and unexpected.
- There were no formal assurance systems within the service.
- There were no formal processes to manage current or future performance within the service.
- There was no programme of clinical or internal audit to monitor quality or operational processes, and there were no systems to identify where action should be taken.
- We requested a copy of the service's risk management policy. However, the document that was provided to us was merely guidance on what to do in the event of an accident within the service.

Inadequate

Diagnostic imaging

- The service did not have a risk register. There were no arrangements for identifying, recording or managing risks, issues and mitigating actions. The provider's main concern was decline in demand for plain-film X-ray services.
- The provider's incident reporting policy contained information for staff about what to do in the event of a radiation incident.

Managing information

- There was no monitoring or reporting of service performance measures.
- There was no provision to patients of any statement that included terms and conditions of the service being provided.
- There were no arrangements to ensure the availability, integrity, or confidentiality of identifiable data or records; medical records kept were insufficient and were not held securely.

Engagement

- The service gathered patients' views by asking some to complete a survey following their attendance. The survey form comprised six closed questions and a space for additional comments. We reviewed seven patient surveys, and all respondents were very positive about the service.
- The provider told us that she had added current magazines to the waiting room following feedback from a patient survey.
- There were no formal systems of staff engagement, but the provider told us that she spent time with her reception staff every time she was on site thus giving them opportunities to contribute ideas or raise any concerns.

Learning, continuous improvement and innovation

- The service had decreased in size in recent years, and the provider was considering retirement, which would mean closure of the X-ray service. There was therefore no focus on continuous learning, improvement, or innovation.
- The service did not participate in any internal or external reviews.

Outstanding practice and areas for improvement

Areas for improvement

Action the provider MUST take to improve

- The provider must ensure that there is a formal recruitment process for staff, including checking of references, curriculum vitaes, or photo ID and disclosure and barring (DBS) checks.
- The provider must ensure that there is appropriate training for each staff member working at the service and that this training is recorded.
- The provider must ensure that appropriate patient ID checks are performed and the Ionising Radiation (Medical Exposure) Regulations (IR[ME]R) 'Pause and Check' operator checklist or similar is used before carrying out X-ray procedures.
- The provider must ensure that risks and alternative procedures are discussed with patients before carrying out X-ray procedures.
- The provider must ensure that consent to procedures is obtained from patients prior to X-ray.
- The provider must ensure that the radiographer takes relevant patient histories and clinical information from the referrer when X-rays are requested.
- The provider must ensure that the radiographer carries out appropriate assessment of the referrer's rationale for referral and clinical question to be answered and records her justification for patient exposure.
- The provider must ensure that the radiographer uses the dose that is as low as reasonably practicable (ALARP) when carrying out x-ray procedures, in line with IR(ME)R guidance.
- The provider must ensure that the radiographer records Dose Area Products (DAPs) for patients who have undergone X-ray procedure, in line with IR(ME)R guidance.
- The provider must keep detailed and correct patient records.
- The provider must ensure that the radiographer decontaminates her hands before and after contact with patients and equipment.
- The provider must ensure that staff understand what comprises a clinical incident and introduce a comprehensive process for learning from incidents.
- The provider must carry out internal and clinical audits.
- The provider must ensure that clinical guidance that includes care of deteriorating patients is available for the radiographer and support staff.
- The provider must ensure that effective systems and processes of accountability and governance are implemented within the service.
- The provider must ensure that risks to patients and the service are identified, assessed, monitored, and recorded appropriately.
- The provider must ensure that the radiographer has the competencies and skills to undertake the role of radiation protection supervisor (RPS) or that a suitable, named RPS is engaged by the service.

This section is primarily information for the provider

Requirement notices

Action we have told the provider to take

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

Regulated activity	Regulation
Diagnostic and screening procedures	Regulation 11 HSCA (RA) Regulations 2014 Need for consent The provider did not follow Society of Radiographers (SoR) clinical guidelines, in that she did not explain risk, offer alternative imaging modalities where appropriate, or keep any record of patient consent.

This section is primarily information for the provider

Enforcement actions

Action we have told the provider to take

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

Regulated activity	Regulation
Diagnostic and screening procedures	Regulation 12 HSCA (RA) Regulations 2014 Safe care and treatment The provider failed to comply with Ionising Radiation (Medical Exposure) Regulations (IR[ME]R) in respect of responsibility for the decision to X-ray, training, recording of Dose Area Product (DAP), keeping correct medical records, justification of exposure to radiation, or ID checking, thus exposing patients to potential harm. The provider did not follow hand hygiene procedures.

Regulated activity	Regulation
Diagnostic and screening procedures	Regulation 17 HSCA (RA) Regulations 2014 Good governance The provider failed to establish systems or processes to assess, monitor and improve the quality and safety of the services provided or to assess, monitor and mitigate the risks relating to the health, safety and welfare of service users, or to maintain suitable records in respect of patients or management of the regulated activity.

Regulated activity	Regulation
Diagnostic and screening procedures	Regulation 19 HSCA (RA) Regulations 2014 Fit and proper persons employed The provider had not carried out any checks of persons employed to establish that they were of good character or that they had the qualifications, competence, skills and experience necessary for the work to be performed by them. There were no staff files and no evidence of any staff training.