The Newcastle Clinic

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	**Requires improvement**
Are services safe?	**Requires improvement**
Are services effective?	**Not sufficient evidence to rate**
Are services caring?	**Good**
Are services responsive?	**Good**
Are services well-led?	**Requires improvement**

Mental Health Act responsibilities and Mental Capacity Act and Deprivation of Liberty Safeguards

We include our assessment of the provider's compliance with the Mental Capacity Act and, where relevant, Mental Health Act in our overall inspection of the service.

We do not give a rating for Mental Capacity Act or Mental Health Act, however we do use our findings to determine the overall rating for the service.

Further information about findings in relation to the Mental Capacity Act and Mental Health Act can be found later in this report.

Summary of findings

Letter from the Chief Inspector of Hospitals

The Newcastle Clinic is operated by Newcastle Clinic Ltd . The Newcastle Clinic had provided a magnetic resonance imaging (MRI) service from Newcastle since 2007, primarily to offer an open sided MRI service to the private health sector in the North East of England and Scotland and to assist local NHS Trusts on an as required basis. The open design of the equipment was especially suited to accommodate patients that were claustrophobic or obese or due to their size or condition or could not tolerate a conventional MRI scanner.

In 2011 a new open sided scanner was commissioned and installed producing imaging of a much higher quality than had been achieved before. In 2013 agreements with North East commissioning support (NECS) were put in place to offer general practitioners (GP's) direct access to the service through the special funding request (SFR) process for patients who fitted specific criteria.

The service provided mmagnetic resonance imaging (MRI) which is a medical imaging technique used in radiology to form pictures of the anatomy and physiological processes of the body in both health and disease. MRI scanners use strong magnetic fields, magnetic field gradients, and radio waves to generate images of the organs in the body. This service was provided to both adults and children.

The service provided image intensification. The Newcastle Clinic offered nerve route blocks(NRB) and facet joint injection (FJI) for pain relief and diagnostic purposes since 2007 to the private health sector. Local agreements are also in place to receive referrals from local NHS trusts.

The service had a consultant led ultrasound service which had been in place since 2011, receiving referrals primarily from local physiotherapists.

The service provided an Ultrasound scan service for adults and children. An ultrasound scan, is a procedure that uses high-frequency sound waves to create an image of part of the inside of the body. An ultrasound scan can be used to monitor an unborn baby, diagnose a condition, or guide a surgeon during certain procedures.

We inspected only the MRI part of this service using our comprehensive inspection methodology. We carried out the announced part of the inspection on 13 November 2018.

The building had an entrance lobby and reception desk, a patient waiting area with access to same sex and disabled toilet facilities. There were 13 consultation/treatment rooms and diagnostic facilities consisting of a MRI scanner room with a supporting MRI control room, a laser ultrasound room and an X-ray room. The first floor was used as office accommodation.

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 **Requires improvement** overall.

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

- The service had a policy and procedure for risk management, however, the service did not have a risk register for either corporate or patient risks.

Summary of findings

- All Gadolinium contrast consent forms and MRI safety forms should be signed by the radiographer. During inspection we found not all computer based MRI safety records and Gadolinium contrast consent forms had been signed by a radiographer.
- Radiographers should sign the appendix at the back of the policy for the administration of Gadolinium contrast to say they had read it. During inspection we reviewed the policy and none of the radiographers had signed to say they had read it.
- The service should have an incident reporting system. We saw evidence three incidents involving patients had been recorded in the accident book but not as incidents.
- During inspection a local rules document for staff was reviewed, it was out of date having last been updated in 2017 and scheduled for review in August 2018. A MRI local rules document outlined local systems of work and safety practices which all staff were expected to have read and signed to say they understood them.
- The fire record test book with times and dates when the evacuation plan had been tested could not be found during the inspection.
- During inspection the services` policy for consent to examination or treatment with reference to the mental capacity act was reviewed and found to be out of date. The review date had been April 2018. No radiography staff had signed to say they had read the policy in the first instance.
- The service did not have a business continuity plan.
- During inspection we checked 22 paper copies of policies, procedures and guidance documents and found 21 were out of date.

We found the following areas of good practice:

- The service had the only open sided MRI scanner in the north of England.
- The service reported MRI results either on the same day for hospital inpatients or within three to five working days for other referrals.
- The environment and equipment was visibly clean.
- MRI safe equipment was clearly labelled.
- MRI safety notices were clearly displayed.
- MRI staff received positive patient feedback from patients who had been scanned.

Following this inspection, we told the provider that it must take one action to comply with the regulations and that it should make six 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.

Sarah Dronsfield

Head of hospital inspections North East.

Summary of findings

Our judgements about each of the main services

Service	Rating	Summary of each main service
Diagnostic imaging	Requires improvement 	We found the following issues that the service provider needs to improve: • The service did not have a risk register for either corporate or patient risks. • Not all computer based MRI safety records and Gadolinium contrast consent forms had been signed by a radiographer. • None of the radiographers had signed the appendix at the back of the Gadolinium contrast policy document to say they had read it. • There was no incident reporting system. • The local rules document for staff was out of date having last been updated in 2017 and scheduled for review in August 2018. • The fire record test book with times and dates when the evacuation plan had been tested could not be found during the inspection. • The policy for consent to examination or treatment with reference to the mental capacity act was out of date. The review date had been April 2018 and no radiography staff had signed to say they had read the policy. • The service did not have a business continuity plan. • During inspection 21 of the 22 paper copies of policies, procedures and guidance documents were out of date. We found the following areas of good practice: • The service had the only open sided MRI scanner in the north of England. • The service reported MRI results either on the same day for hospital inpatients or within three to five working days for other referrals. • The environment and equipment was visibly clean. • MRI safe equipment was clearly labelled. • MRI safety notices were clearly displayed. • MRI staff received positive patient feedback from patients who had been scanned.

Summary of findings

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Requires improvement

The Newcastle Clinic

Services we looked at: Diagnostic Imaging

Summary of this inspection

Background to The Newcastle Clinic

The Newcastle Clinic is operated by Newcastle Clinic Ltd . The clinic is part of the Oak Apple Group based in Leeds. The service opened in 2007. It is a private clinic in Jesmond, Newcastle, Tyne and Wear. The clinic primarily takes MRI referrals from NHS trusts, GP`s and private referrals from consultants.

The clinic has had a registered manager in post since 1 October 2010. The service is registered for the following regulated activities:

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

The clinic also offered image intensification, nerve route blocks (NRB) and facet joint injection (FJI) for pain relief and diagnostic purposes and a consultant led ultrasound service.

We did not inspect these services.

We conducted an unannounced an inspection of the MRI part of the service on 13 November 2018.

The previous CQC inspection of this service was in September 2013. The service had met the fundamental standards inspected against at that time.

Our inspection team

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

Information about The Newcastle Clinic

The clinic is registered to provide the following regulated activities:

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

During the inspection, we inspected the MRI part of the clinic. We spoke with five staff including; the managing director, clinical coordinator, business development manager and two radiographers. We spoke with one patient. We reviewed 38 Newcastle clinic patient feedback cards, six sets of patient records and five staff records.

There were no special reviews or investigations of the service ongoing by the CQC at any time during the 12 months before this inspection. This was the services first inspection since September 2013, which found that the service had met all standards of quality and safety it was inspected against.

Activity (January 2018 to November 2018)

- In the reporting period January 2018 to November 2018 the MRI section of the service saw 1346 patients, 1029 were NHS referrals and 317 were private patients. The provider had only two child referrals who were aged five and ten in the same period.
- On average there were 16 or 11% cancellations of scan appointments per month. These were due to patients not tolerating the scan or not turning up for the appointment. None were due to mechanical failure of the scanner.

The service employed a clinical coordinator and an assistant radiography manager on a full-time contract. An assistant radiographer was employed by the service working Wednesday, Thursday and Friday each week. There were two radiographers employed by the service

Summary of this inspection

one worked two days per week and one for one day and week, they also covered for holidays. There were four receptionists covering the clinic opening hours between 7.30am and 8pm. They worked alternative weekends.

There were five bank staff radiographers who worked on an as required basis dependent upon demand. There were three bank registered general nurses(RGN) and five bank health care assistants(HCA`s) who worked on an as required basis dependent upon demand.

This equated to 2.7 whole time equivalent (WTE) radiologists and 0.5 WTE who worked under practicing privileges. Nursing staff also worked at the clinic as well as having bank staff.

Track record on safety

- No Never events
- No clinical incidents, no incidents with harm, none with low harm, none with moderate harm, none with severe harm and no deaths.
- There were no reports of serious injuries

One complaint was recorded.

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	Not rated	Good	Good	Requires improvement	Requires improvement
Overall	Requires improvement	Not rated	Good	Good	Requires improvement	Requires improvement

Requires improvement

Diagnostic imaging

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

Are diagnostic imaging services safe?

Requires improvement

We rated it as requires improvement because;

- The service did not have a system to record and report incidents.
- The policy for reporting incidents was out of date.
- The policy for the administration of Gadolinium contrast had not been signed by any of the radiographers to say they had read it.
- The hand hygiene audits in the audit folder in the MRI office stated the audits were done quarterly but from the dates on the audit records they appear to have been done every six months.
- The fire record test book with times and dates when the evacuation plan had been tested could not be found during the inspection.

However, we did find the following examples of good practice;

- All staff mandatory training was up to date at the time of the inspection.
- There was an identified appropriately trained safeguarding lead.
- Staff safeguarding training was up to date.
- During inspection all areas of the clinic appeared visibly clean and well looked after.

Mandatory training

- Mandatory training requirements for NHS staff who worked as bank staff at the Newcastle Clinic were monitored through the NHS electronic staff record (ERS) portal. The clinical coordinator regularly checked the portal which flagged when refresher training was required. The dates were supplied to an external training provider who attended the Newcastle clinic and delivered the training to those who required it.
- It was the responsibility of all bank staff had to maintain up to date basic life support(BLS) training which included paediatric life support, moving and handling, risk management training, fire training. We saw evidence of this in the staff files we reviewed.
- Members of staff employed by the Newcastle Clinic were given annual mandatory training by an external training provider. We saw evidence of 100% compliance in the staff files we reviewed.
- During inspection we saw evidence mandatory training for all staff either employed by the service or working on the bank was up to date.

Safeguarding

- The service had an identified appropriately trained safeguarding lead. We saw evidence they were trained to children's safeguarding level three.
- In relation to children's safeguarding the service had three staff trained to level three, two trained to level two and four trained to level one. This met intercollegiate guidelines.
- In relation to adult safeguarding the service had three staff trained to level two and all staff were trained to level one. This met intercollegiate guidelines

Requires improvement

Diagnostic imaging

- Policies and procedures were in place for safeguarding vulnerable adults and children which met intercollegiate guidelines. Children were not allowed to be in any part of the clinic unaccompanied. We saw evidence in the Newcastle Clinic appointment letter which explained this.
- Although the service had not made any safeguarding referrals all staff we spoke with could explain how and why they would make a referral.

Cleanliness, infection control and hygiene

- During inspection all areas of the clinic appeared visibly clean and well looked after. There were bottles of alcohol hand gel situated around the clinic for staff and patients to use.
- We saw staff worked bare below elbows and were observed to clean their hands using the alcohol gel after patient contact.
- Newcastle clinic contracted a professional cleaning company to clean the premises and environment. There were three monthly audit checks carried out both with clinical staff and the supervisor. Each member of staff was kept up to date with findings and any actions from the infection control and hand hygiene audits. The audit findings were shared with staff through an e mail circulation.
- During inspection we saw the results of an infection control audit carried out by the clinical coordinator in May 2018 which covered hand hygiene, clinical procedure, sharps handling and disposal, waste disposal, environment and cleaning products. The audit results showed 100% compliance. The next review was due March 2019.
- We saw evidence of hand hygiene audits in the audit folder in the MRI office. The information in the folder stated the audits were done quarterly but from the dates on the audits they appear to have been done every six months.
- We saw evidence of a cleaning audit from August 2018 which identified issues with dust on skirting boards and under patient beds. This was addressed through an action plan agreed by the service with the cleaning company. This was monitored by Newcastle Clinic staff who conducted checks after cleaning had been completed.
- We observed staff cleaning down a bed and MRI coils with clinical wipes after a patient had received a MRI scan.
- We reviewed a procedure document for cleaning the MRI facility which was in date and due for review in 2020. We saw evidence of a cleaning record of the MRI facility which was carried out twice weekly by MRI staff which was completed appropriately.
- We saw evidence of an infection protection control methicillin-resistant Staphylococcus aureus (MRSA) policy which detailed use of personal protective equipment, hand hygiene and cleaning. The policy was in date and due for review in 2020.
- Staff told us if a referral was made for an infectious patient they would be scanned at the end of the list. The room and equipment would then be cleaned in accordance with the policy.

Environment and equipment

- The waiting area for patients appeared visibly clean. There was comfortable seating with tea and coffee making facilities available.
- The MRI scanner had been in place since 2010. The scanner was subject to four services a year. We saw evidence of the service records which were held on a computer database. The service had a contract with an external company to carry out repairs to the scanner. There was a service level agreement for the company to attend within two hours from when they were notified of any fault.
- There was evidence only MRI compatible equipment was situated in the MRI scan room. All relevant MRI equipment was labelled in line with Medicines and Healthcare Products Regulatory Agency MHRA recommendations being labelled MR Safe.
- The scanning bed was at a fixed height to allow side to side positioning of the patient. There were MRI safe steps next to the scanner for the patient to get on to the scanning bed.
- If the patient was not mobile there was a height adjustable trolley which could be used to take the patient into the scan room and either raised or lowered to the height of the scan bed.

Requires improvement

Diagnostic imaging

- The door to the scanning room had warning signs displayed stating, “strong magnetic field”, “no pacemaker”, “no loose metal objects” and “this magnet is always on” to warn people who had not undergone a safety check not to enter.
- Patients who were being scanned were provided with disposable ear plugs to reduce the noise of the scanner. Ear defenders were not required because the lower strength magnet in the open scanner did not create as much background noise as a conventional scanner while in operation.
- If a patient became unwell or suffered a cardiac arrest there was a clear process if a patient deteriorated during a scan.
- There was a portable defibrillator machine mounted on the wall next to the X-ray screening room. The defibrillator was checked during inspection. The user manual was behind the defibrillator and there was a sticker outlining it had been installed in January 2018. The expiry date of the pads was October 2019.
- Staff we spoke with told us the defibrillator was checked weekly and this was documented.
- The process to follow if a patient deteriorated during a scan and needed medical assistance was to dial 999 to obtain an emergency ambulance. There was a MRI safe trolley which could be used to transfer an ill patient from the scan room to await an ambulance.
- We saw a fire evacuation plan was displayed near the fire control panel in the entrance lobby. The fire exits in the building were clearly marked. We saw evidence there had been a check of the fire alarm system in April 2018 by the company which had installed it. The fire record test book with times and dates when the evacuation plan had been tested could not be found during the inspection.

Assessing and responding to patient risk

- There was a risk assessment in place in relation to the administration of Gadolinium, which is a medical dye injected into a patient during a scan to enhance the image of organs, and a clear standard operating procedure for managing an adverse reaction which staff were aware of.
- Staff told us if a patient had an adverse reaction to Gadolinium contrast this would be recorded in the incident book held in reception. Staff told us they had never had a patient have a patient have an allergic reaction to Gadolinium contrast.
- Staff had access to an epinephrine autoinjector, which is a medical device for injecting a measured dose or doses of epinephrine by means of autoinjector technology and medicine used for the treatment of anaphylaxis and symptomatic control of all allergic conditions responsive to antihistamines if a patient did have an allergic reaction to Gadolinium.
- The service kept records of dates of expiry of Gadolinium contrast, the epinephrine autoinjector and the medicine used for the treatment of anaphylaxis to ensure they were not out of date.
- In the 12 months prior to this inspection no patients had required to be transferred from the clinic to another health care provider either before, during or after a scan.
- We saw evidence all staff had received basic life support training which included paediatric life support. The resuscitation policy was reviewed during inspection and was found to be in date.
- If a patient became ill during a scan staff told us they would immediately ring 999 for an emergency ambulance.
- Staff told us they rarely got referrals for pregnant patients. However, if the referral letter indicated the patient was 12 weeks pregnant or less, they would not scan the patient unless there was a medical necessity to do so which they would confirm with the referrer. If a patient who was pregnant attend for a scan they would fill out an informed consent form and safety information questionnaire including the risks involved both of which would be scanned on to the patient notes.
- Staff we spoke with could not remember a time when they had scanned a pregnant patient, therefore, we could not review any records of this category of patient. We did review a blank consent form which contained relevant sections to fill out to identify any patient risks.

Nurse staffing

Diagnostic imaging

- Bank nursing staff were employed under independent practitioner status, and were utilised in accordance with the clinics demands. Clinic appointments were booked with a minimum of 48 hours' notice which gave sufficient time to ensure adequate cover was available.
- The clinical coordinator told us appointment lists were usually drawn up a week in advance which gave enough time to contact bank staff and inform them when they would be required to work.
- The service had 0.5 whole time equivalent (WTE) staff which was one nurse on a part time contract.
- In the three months prior to this inspection bank nurses had been used on five shifts and health care assistants on eleven shifts. No agency staff had been used during this period.
- Staffing levels and skill mix were planned, implemented and reviewed to keep the patients and service users safe. Any identified staff shortages were responded to as quickly as possible to ensure patients safety was maintained.
- The clinical coordinator told us in the event of short time notification of staff sickness when alternative staff could not be contacted they would performing a nursing role.

Medical staffing

- Radiography staff were employed on defined contracts to ensure the service was effectively and safely operated based on the service operating at maximum capacity. All staff employed were senior within their profession.
- The service had 2.7 WTE radiographers. One was full time, three-part time and four were on zero hours contracts.
- Staff told us usually two radiographers worked together when scanning a patient. On occasions there would be only one radiographer while another worked elsewhere in the clinic.
- Staff told us if any problems arose the lone radiographer would telephone a colleague to return and assist them.
- During inspection we did see evidence of a lone working policy which was in date and due for review in April 2019.
- There was no evidence of a lone worker risk assessment or standing operating procedure.

Records

- The service received both paper and e-mailed patient information. We reviewed five computer based MRI safety records and Gadolinium contrast consent forms which had been paper based. All had been scanned on to the patient records. One was found not to have been signed by a radiographer.
- We reviewed six paper patient records. All contained a referral letter, a completed patient safety questionnaire and a MRI report. No details appeared to be missing.
- We saw evidence safety questionnaires were completed by family members or friends who accompanied a patient to the scan. Copies of the questionnaire were scanned on to the patient record.
- Patient information records were held in a four-drawer filing cabinet locked by key and in a secure first floor office. The key was held by the Clinical Coordinator and only the senior radiographer could open the filling cabinet if they were not on duty.
- Patient referrals came to the clinic by e-mail, fax, post and by courier from GP`s, NHS Trust`s and independent companies. The clinical coordinator told us they would be notified by the referrers a week in advance so appointment lists could be drawn up and patients informed as soon as possible with the time and date of their scan appointment.
- We saw evidence patients were on average given their appointment three to five working days after the clinic received the referral.
- If the patient had been an inpatient and had arrived from a NHS trust the scan results were provided on the same day by email.
- If a trust had submitted paper referrals once the scan report had been completed this was attached to the

patient notes. The clinical coordinator told us once a week they would return all the paper patient notes with scan reports attached to the NHS trust which made the referral and have them signed for.

- While on inspection we saw a collection of patient notes delivered by courier in a secure tagged bag from a NHS trust. The clinical coordinator told us notes from that trust would be returned by courier in a sealed bag once the scans had been completed.
- The clinical coordinator told us emailed referrals would have the MRI report emailed back to the referrer.
- Postal referrals would have the MRI and accompanying notes returned by recorded delivery. The signed for receipt was stored at the clinic so a record could be maintained as to who had signed for the notes and MRI report.
- We saw staff checking and confirming patient information prior to a scan. Staff checked the patients name, address, date of birth, confirmation on which side the scan would be done, confirmed the information from the patient in the safety questionnaire and confirmed consent.
- The business development manager told us the clinic had undertaken an audit of MRI reports and the letters back to the referrers because issues had been identified with the accuracy of the information which differed between the electronic patient records and the letters. Any identified errors had been reported back to the staff member concerned by email.
- We saw evidence through the audit system during the three months prior to the inspection the error count in letters back to referrers had been zero.
- During inspection the MRI audit covering 2- 7 July 2018 was reviewed. Thirty patient records were reviewed which covered; patient ID, request card, full name, date of birth, address, area to be scanned, clinical history, referrer full name and signature, safety questionnaire, signature of patient and radiographer and correct protocol. There were only two errors, one safety questionnaire was missing and one date of birth had been incorrectly recorded.

Medicines

- The service held medicines which included an epinephrine autoinjector, which is a medical device for injecting a measured dose or doses of epinephrine by means of autoinjector technology and medicine used for the treatment of anaphylaxis and symptomatic control of all allergic conditions responsive to antihistamines.
- Patients were advised not to bring medication to the clinic unless they needed to take the medication whilst they were there.
- Patients were asked by staff when making an appointment if they took blood thinning medication as it was necessary to stop those five days before procedures as it could be a health risk to the patient.
- The service used Gadolinium contrast which is a dye injected into the patient during a scan to highlight organs or the structures of the body. Gadolinium contrast dosage is calculated by patient weight. Patients were weighed at the clinic prior to receiving the contrast. There were prefilled syringes kept locked in the MRI control room for staff to use. The amount to be administered by syringe was patient weight dependant.
- If Gadolinium contrast was to be used in a scan the patient would be sent out renal function questionnaire which had to be returned prior to the scan appointment along with the safety check list. If required, the patient would have a blood test to check their kidney function, if needed, prior to the scan.
- Prior to the scan and if Gadolinium contrast was going to be used, the patient would be given an explanation as to what it is and why it was required before obtaining their written consent to use it. The lot number of the contrast and expiry date was recorded on the patient record.
- The Gadolinium contrast was injected by hand, no pump injectors were used. There was evidence all radiographers have had cannulation training. Radiographers used butterfly needles for administering Gadolinium contrast.

Requires improvement

Diagnostic imaging

- During inspection we reviewed the policy for the administration of Gadolinium contrast which was current and due for review in 2020. None of the radiographers had signed the appendix at the back of the document to say they had read and understood it.

Incidents

- The service had an incident report policy document which had three distinct parts. The first part comprised a brief general policy statement for incident reporting within the Newcastle Clinic. The second was specific procedure for reporting and dealing with serious incidents and the third outlined the arrangements in respect of all other incidents.
- We did not find an incident reporting book but there was an accident book. We saw evidence three incidents involving patients had been recorded in the accident book. One related to a fall, one related to a foot stool slipping, and one related to a patient fainting post scan. There was evidence each "accident" had been reviewed, the cause identified and remedial action taken.
- There was a procedure for reporting and dealing with serious incidents which included; definition of serious untoward incidents, reporting arrangements, action to be taken following reporting of serious untoward incidents, subsequent action and monitoring. The service had not report any incidents.
- The was a procedure for reporting and investigation of untoward incidents and near misses which included an introduction, a definition of incident categories, reporting arrangements, incident investigation, Reporting of Injuries, Diseases and Dangerous Occurrences Regulations 2013 (RIDDOR) reporting, monitoring and feedback and an appendix listing external organisations.
- The incident reporting policy had been finalised in April 2018 and was due for review in April 2019.
- In the previous 12 months prior the inspection the service had not made any duty of candour notifications and not recorded any never events or serious incidents.
- A Never Event is defined as; a serious, largely preventable patient safety incident that should not occur if the available preventative measures have been implemented by healthcare providers.
- The professional duty of candour places a responsibility for every healthcare professional to be open and honest with patients when something that goes wrong with their treatment or care causes, or has the potential to cause, harm or distress. This means that healthcare professionals must; tell the patient (or, where appropriate, the patient's advocate, carer or family) when something has gone wrong, apologise to the patient (or, where appropriate, the patient's advocate, carer or family), offer an appropriate remedy or support to put matters right (if possible) and explain fully to the patient (or, where appropriate, the patient's advocate, carer or family) the short and long-term effects of what has happened.
- Healthcare professionals must also be open and honest with their colleagues, employers and relevant organisations, and take part in reviews and investigations when requested. They must also be open and honest with their regulators, raising concerns where appropriate. They must support and encourage each other to be open and honest, and not stop someone from raising concerns.

In the previous 12 months prior to the inspection the service had not reported any ionising radiation medical exposure regulations(IRMER) or ionising radiation regulations(IRR) reportable incidents.

Are diagnostic imaging services effective?

Not sufficient evidence to rate

The effective domain was not rated.

Evidence-based care and treatment

- We saw evidence in patient notes and through speaking with staff that patients had their needs assessed and their care planned and delivered in line with evidence-based, guidance, standards and best practice. This was done though the referral procedure and safety questionnaire.

- As the scanner was the only open sided scanner in the north of England there was evidence technology and equipment had enhanced the delivery of effective care and treatment for patients who otherwise would not have been scanned.

Nutrition and hydration

- During inspection we saw evidence of staff offering patients hot and cold drinks before and after scans.
- Due to the short appointment times and type of service offered nutrition was not provided.

Pain relief

- Staff we spoke with told us they did not manage patient pain in relation to MRI scans.
- If a hospital inpatient attended the clinic for a scan they would be accompanied by a nurse from the referring hospital who would deal with the patient's pain if required. The safety questionnaire, which included questions about patient medication, would be completed. Staff told us if there were any concerns about the potential effect of the medication on the patient during the scan they would discuss this with the referrer.

Patient outcomes

- During inspection we saw evidence of a patient care pathway clinical audit carried out in September 2018 across all the services at the Newcastle Clinic and applied to both nursing and radiology staff. The findings were, all the staff thought the information on the pathway was valid, 778 pathways were reviewed 27 files had admission dates and times missing, 30 files had discharged time missing, every pathway had patient consent recorded, the WHO check lists were all signed, all surgical outpatient's records had been correctly completed by consultants and 18 declarations for female patients of childbearing capacity had not been signed by the radiology operator.
- We saw evidence the findings were fed back to all staff and the managing director. There was agreement with the management team to re-evaluate the findings in five months through another audit, although there was no improvement plan in place.

Competent staff

- Newcastle Clinic ran an induction and training course for new employees and bank staff to support them whilst they orientated themselves within the clinic and their workplace.
- All new staff regardless of grade or profession had to attend the clinics induction course. There was evidence of this in all staff files we checked.
- The induction process for Nursing Staff and HCA`S were staff who had been given a position within the Newcastle clinic met the Clinical Director at an agreed time prior to starting work that day. The new member of staff was introduced to the clinics permanent staff including the, reception staff, MRI manager and staff, business development manager and the managing director.
- During the induction the manager or preceptor of the new staff member outlined each area involved in the admission of a patient into the clinic. New staff were shown round the immediate area of work to familiarise themselves with relevant areas such as stock cupboards and outside locations for medical and domestic waste. The staff member was told about their duties and responsibilities including: job description, department organisation chart, and hours of work and an explanation about the telephone intranet systems.
- Staff were informed where to find important information documents including, policies, protocols, procedures and care pathways. It would be established if an office or drug keys were required, where they were held, by who and if they need to be signed for.
- The Clinical Coordinator explained the staff member would be required to sign confidentiality statement.
- Staff were given an explanation of fire procedures including, the location of extinguishers, fire panel and the action to be taken on hearing a fire alarm, what the evacuation procedure was and what action to take if staff found a fire.
- Staff were given a help phone numbers for supervisors and managers which they could ring if they had any issues they wanted to discuss. Staff were also given, resuscitation guidelines including emergency equipment location, procedure for summoning help,

information on general standards of behaviour and conduct with expected, dress code, information on communication including the patient's information board, record management including, security of patient records, Data Protection Act and responsibilities, Newcastle Clinic statement of purpose, policies, an explanation how to report an incident and location of the incident reporting forms. Staff were provided with Health and Safety guidelines and information in relation to waste management and infection control.

- The service had a process for checking Bank Staff. The applicant had to clearly demonstrate on their application form how they met the clinics employment criteria and failure to do so could result in them not being short listed. One of the application criteria was if the applicant was a currently a registered nurse level one on the live nursing midwifery council (NMC) register and possessed nursing experience if applicable.
- As part of the recruitment and selection process the Newcastle Clinic carried out Enhanced Disclosure check (DBS) checks. Staff were required to produce evidence of their independent practitioner status.
- There was evidence in the six staff records checked during inspection there were current DBS checks in place. There was no documented process or risk assessment if a DBS check was returned with concerns.
- References would be requested from previous employers where appropriate. Personal identification including passports and driving licenses were checked. We saw evidence of this in the six staff records we checked during inspection.
- Bank Radiography staff had an individual induction which included orientation to the local policies and procedures.
- In the 12 months prior to inspection the appraisal rate for the radiographers was 75%. The appraisal rate for the one clinical coordinator was 100%. The reason for this was one of the members of staff had been on maternity leave.
- We reviewed three completed appraisals. Staff were assessed against the following areas; communication and interpersonal skills, quality of work, job knowledge and expertise, attitude, ethics, self-development and growth. The three members of staff had rated themselves as excellent across the assessment areas which had been confirmed by the managing director. There was a section for an annual declaration and review covering professional requirements to fulfil the role. There were two sections one to declare any criminal convictions and one to confirm mandatory training was up to date. None of the staff declared any issues.
- We saw evidence in staff files in the last 12 months the four radiographers and the clinical coordinator had their professional registration checked including restrictions on practice and all were found to be current.
- We reviewed four staff peer appraisals which covered seven areas which were, patient ID and process confirmed, safety questionnaire completed, patient detail correctly added to the system, correct positioning and coil selection, correct protocol selected, diagnostic images acquired and post processing complete. All four appraisals showed each of the assessment areas had been correctly completed by the staff.
- We reviewed a local rules document for staff. It appeared to be out of date having been created in 2015 and last scheduled for review and update in August 2018. At the time of the inspection the document was still under review with Radiation Protection and Medical Physics. The local rules document outlines systems of work and safety procedures.
- Two of the MRI staff told us they had recently attended a MRI safety course and all the MRI staff regularly attend UK radiological and radiological oncology congress(UKRC) conferences where they received up to date information on current practice.
- Staff we spoke with told us they felt if they requested funding and support to obtain further qualifications they would be supported by the management team.
- There was evidence all radiographers have had cannulation training. Radiographers used butterfly needles for administering Gadolinium contrast. Their competence was assessed by the clinical coordinator.

Requires improvement

Diagnostic imaging

- Newcastle Clinic staff as part of their contract of employment had to disclose details of any other providers that they may engage in any form of employment outside of Newcastle Clinic, details of which were recorded. Should a member of staff have been suspended from duty by Newcastle Clinic immediate notification would be given to all providers that member of staff was recorded as being employed by.

Seven-day services

- Newcastle Clinic was open Monday to Thursday 7.30am to 8pm, Friday 7.30am to 6pm, Saturday 7.30am to the last appointment and Sunday 8am to the last appointment. The service was closed on bank holidays and the Friday before Christmas re opening on 3 January.

Access to information

- During the inspection we saw MRI scan images were transferred onto computer discs which were returned to the referrer with the patient notes usually within seven to ten days.
- Back up discs were used to back up the scan information in the event of it being lost. There was the ability transfer the images to a computer work station which the radiographer referred to when reporting the scan findings.

Consent and Mental Capacity Act

- Staff told us the service did not receive many referrals for patients who were suffering mental ill health. We saw evidence the referral letter would inform the service if the patient had any mental capacity issues. If this was the case staff told us they would contact the referrer to discuss the information in more depth.
- We saw evidence staff had received training in consent and the Mental Capacity Act
- Patient consent was confirmed when the radiographers verified the information in the patient safety questionnaire. Consent for children to undergo a scan was obtained by a parent or guardian accompanying the child

During inspection we reviewed the services` policy for consent to examination or treatment with reference to the mental capacity act. The policy was out of date. The review date had been April 2018. No radiography staff had signed to say they had read the policy. After this had been pointed out to managers we later saw evidence all radiography staff had signed to say they had read the policy.

Are diagnostic imaging services caring?

Good

We rated it as good because;

- There were high levels of positive patient feedback.
- The reception staff were trained chaperones who could support female patients if required.
- There were single sex changing rooms and toilets.
- Staff understood fully the type of patient who attended the clinic.
- Patients were provided with background information and a number to call if they had any concerns prior to the scan.

Compassionate care

- During the inspection we reviewed 38 Newcastle clinic patient feedback forms. There were no negative comments about the care or service provided. Some patient's comments were, "Very pleasant and professional people throughout the clinic", "All staff were excellent and made me feel at ease", "Very good staff, felt relaxed and calm" and "All staff are very helpful, informative and empathetic".
- The staff were aware many of the patients would be very anxious about having a scan. Staff told us they would sit with the patient during a scan to reassure them and deal with any concerns to put them at ease.
- During the inspection we spoke to one patient who had been very nervous before the scan and was claustrophobic. They told us they had been happy with the scan; the staff had been caring and there had been the opportunity to ask questions.
- We saw evidence reception staff were trained chaperones who could support patients if they arrived unaccompanied and they wanted a chaperone.

Diagnostic imaging

- There were private changing rooms for patients who needed to change into a gown.
- We saw patients were offered headphones to listen to music while being scanned. There was a selection of music for patients to choose from.

Emotional support

- Staff we spoke with understood fully the type of patient and why they had attend for a scan including the impact that person's care, treatment or condition would have on their wellbeing and on those close to them, both emotionally and socially.

Understanding and involvement of patients and those close to them

- Prior to the patient attending the clinic they would be sent a patient information booklet with the appointment letter and safety questionnaire. The patient information booklet contained colour pictures of the scanner which showed it was different to the conventional scanner in that it was open. This was important for patients with claustrophobia reassuring them they would not be totally enclosed when scanned.
- The booklet contained clinic contact numbers so patients could ring before the scan and discuss any concerns or worries they had.

Are diagnostic imaging services responsive?

Good

We rated it as good because;

- The service provided a tailored service for the individual who required an open MRI scan due to claustrophobia, obesity or suffered from limited mobility.
- Patients were given appropriate information and support regarding their care and treatment prior to procedures using patient information leaflets.
- In the previous 12 months there had been no cancelled appointments due to non-clinical issues.
- The maximum waiting time for a scan appointment was three to five days from receipt of the referral.

Service delivery to meet the needs of local people

- The environment was appropriate and patient centred with comfortable, sufficient seating, single sex and disabled toilets. There were magazines and hot and cold drinks machines in the reception area.
- There was a staffed reception desk where patients registered their arrival before their appointment.
- Local NHS trusts, GP`s and private consultants were aware the service had an open sided MRI scanner through promotion of the service by the management team who had visited NHS and private providers and the services internet page. Scanners of this type were used for patients who typically could not tolerate a conventional scanner and as such the service was receiving patient referrals both locally and from other parts of the country.
- The Newcastle clinic was open Monday to Thursday 7.30am to 8pm, Friday 7.30am to 6pm, Saturday 7.30am to the last appointment and Sunday 8am to the last appointment. The service is closed on bank holidays and the Friday before Christmas re opening on 3 January.
- All information in relation to a patient's care was available in any format upon request by the patient. Historically this had been achieved both "In-House" and outsourcing to a third party. An external translation service had been used and information had been supplied in large print.
- The Newcastle Clinic would be informed through the referral process if he patient required information in a different format of language which enabled arrangements to be made.

Meeting people's individual needs

- The service provided a tailored service toward the individual who required an open MRI scan due to claustrophobia, obesity and the elderly or young who suffered from limited mobility. Referrals were accepted from NHS trusts, general practitioners (GP`s) and private referrals from consultants.

Requires improvement

Diagnostic imaging

- The building and scan room was accessible to wheelchair users and there was a toilet accessible for wheelchair users and disabled patients.
- Requests for a scan or diagnostic procedure referrals were followed up by a pre- assessment questionnaire asking the individual to identify if they have any conditions including allergies preventing them from undergoing a scan or procedure.
- All patients were given appropriate information and support regarding their care and treatment prior to procedures using patient information leaflets posted to the patient before they attended the clinic. If patients had any concerns they were given further advice from the Clinical Coordinator or MRI manager through a phone call. All information was recorded on the patient pre- assessment referral letter.
- Staff always discussed with the patient the reason for their procedure and any medical history the patient had given on admission. All information was documented on the patient's pathway.
- The coordinator in charge of patient care, treatment and support was identified to the patient on arrival. All members of the team were introduced to the patient and told who would be looking after them throughout their time at the clinic.
- Discharge information was given to the patient post treatment and further observations carried out prior to discharge which were recorded on to the patient pathway. Any concerns were noted and appropriate action taken.

Access and flow

- Referrals were accepted from the NHS trusts, GP`s and private referrals from consultants. The service had no service level agreements or contracts. The service was demand driven and being restricted as to the number of scans it could perform by the opening hours of the clinic.
- The service saw on average ten patients per day. Each appointment was 45 minutes.
- We saw evidence patients were contacted and offered alternative dates or times for an appointment which was suitable and convenient for them.
- The service did not prioritise referrals, however, there was a contingency if an urgent or emergency MRI was needed for a hospital inpatient. The clinic would plan this around normal appointment times and move any booked patients to another same day appointment if necessary.
- All referrals were passed to the MRI department for timing and protocol. The patients were always offered the next available appointment.
- In the previous 12 months there had been no cancelled appointments due to non-clinical reasons.
- The managing director told us the service had on average per month 16 (11%) of referral appointments cancelled. It was explained a MRI scan which was not completed because of the actions of the patient or the patient did not attend was recorded as a cancellation.
- We saw evidence the maximum waiting time for a scan appointment was three to five days from receipt of the referral.

Learning from complaints and concerns

- The service had a policy whereby if a patient had a complaint the clinic would deal with it and give a written acknowledgement within two working days unless a full reply could be sent within five working days. A full response would be made within 20 working days.

Between March 2017 and August 2018, the service had received one complaint relating to the MRI services which had been investigated in accordance with the policy. The outcome of the complaint investigation was shared with all MRI staff.

Are diagnostic imaging services well-led?

Requires improvement

We rated it as requires improvement because;

- Of the 22 paper copies of policies, procedures and guidance documents and found 21 were out of date.
- The mission statement and philosophy of care statement was not displayed on any notice boards or on the services internet site.

Requires improvement

Diagnostic imaging

- The service did not have a risk register and risk was not discussed at the quarterly management meetings.
- The service did not have a business continuity plan.

However, we saw the following examples of good practice;

- There was evidence of good team work and staff supporting each other.
- The service was proactive in seeking patient feedback.

Leadership

- The service was led by a managing director. There was a finance director and a director who reported to the managing director. The was a clinical coordinator responsible for all nursing staff and an imaging manager responsible for all radiology staff. There was a business development and reception manager responsible for staff files, appointments, administration and reception staff.
- The service had staff identified in key roles including, head of clinical service, radiation protection adviser, medical physics expert, radiation protection supervisor, senior radiologist, infection control lead.
- Staff we spoke with told us the management team were visible, approachable and helpful.
- Managers were effective and were skilled and qualified to lead the service.

Vision and strategy

- The managing director provided a copy of the providers mission statement which was;

"…to offer high quality MRI, ultrasound, X-ray diagnostic services to both the public and private healthcare market. Delivering this to the highest level of clinical excellence in a fast and professional manner. We will strive to provide superior quality healthcare services that: patients recommend to family and friends, clinicians prefer for their patients, employees are proud of and offering the perfect patient experience."

- Staff we spoke with were not aware of mission statement.
- We did not see the mission statement displayed on any notice boards or on the services internet site.
- The provider had a philosophy of care statement which was on an A4 piece of paper displayed near the clinic main entrance/exit door. The statement outlined the following;

" … at the Newcastle clinic we strive to build upon our reputation to provide services that are tailored to meet our patient's needs. This results in us providing excellent patient centred care by using a holistic and therapeutic approach. We recognise that our patients have the right to have their cultural, emotional and disability needs met here at Newcastle clinic. As a patient of Newcastle clinic, we will make every effort to ensure that you receive the excellent standard of care that you deserve."

- The philosophy of care statement was dated July 2017 and due for review July 2019. The statement was not on display anywhere else in the building and did not appear on the services internet site.
- The managing director told us the service was exploring other diagnostic services they could provide in the future.

Culture

- During the inspection staff told us they felt part of a team and everyone supported each other.
- We observed good team work and support during the inspection.
- There appeared to be an open honest culture
- The Head of clinical services was accessible to staff to discuss issues with.
- The service promoted feedback from patients.

Governance

- Managers and staff, we spoke with told us arranging meetings for radiographers to discuss performance, referrals and patient feedback had been difficult because of the differing work days and start times.
- We saw evidence of managers meetings which were minuted. All staff could access the minutes through the provider intranet site.
- Staff used an A5 diary to leave important messages for each other. They also used a social media group to communicate and discuss issues.

Requires improvement

Diagnostic imaging

- The service held quarterly management meetings which covered all the services provided at the clinic. There was a set agenda for every meeting. The agenda was more focussed on business not governance.
- We reviewed the minutes for the meeting held in September 2018. The minutes reflected the agenda items, actions had owners and there was a clear link to the previous meeting actions.
- All policies and guidelines were evidence based in line with the national institute of clinical excellence (NICE) and the world health organisation (WHO). During inspection we reviewed both hard copies and computer copies of policies, procedures and guidance documents 22 paper copies of policies, procedures and guidance documents and found 21 were out of date and eight computer copies of policies, procedures and guidance documents one was out of date.
- The service had policies relating to; concern and complaints, concern relating to performance, professional behaviour and personal conduct of clinic staff, whistle blowing, safeguarding adults/children policy, and being open, saying sorry when things went wrong, patient confidentially policy, data quality and record keeping polices, storage of patient's records policy, storage of drugs, drawing up of drugs, incident reporting and record keeping.
- There was also an environmental policy, universal precautions, infection control policy, MRSA policy and procedure and a hand hygiene policy.
- As part of the conditions to practice at Newcastle Clinic practitioners had to supply, in hard copy, a valid certificate of insurance in accordance with the Health Care and Associated Professions (Indemnity Arrangements) Order 2014. The expiry date was recorded and diarised. Prior to renewal a reminder was sent to the practitioner requesting, when due, a copy of their new certificate, giving clear instruction that failure to provide this would result in a suspension and withdrawal of practicing privileges.
- To maintain accurate information about their personal performance in line with national guidance on appraisal for doctors and to maintain practising privileges, staff had to ensure the Newcastle Clinic received an appraisal request from the primary employer, a completed copy of which was held on file along with a copy of the final appraisal.

Managing risks, issues and performance

- The service had a policy and procedure for risk management which was in date. The document outlined how to assess risk. However, the service did not have a risk register for either corporate or patient risks. In addition, risk was not included as an agenda item at the quarterly management meetings.
- There was evidence patient risk was assessed through the patient safety questionnaire and referral letters. There was no evidence this information was reviewed to identify themes or to develop mitigation strategies or discussed at management level.
- The service did not have a business continuity plan.
- The managing director told us the only risk to the existing MRI service was another provider in the area obtaining an open sided MRI scanner and offering the same service as the Newcastle Clinic.

Engagement

- Newcastle Clinic carried out patient audits to gain feedback on the quality of its service and to review any areas for improvement. The last patient survey conducted was for July to September 2017. There are no MRI specific surveys.
- Patient comments were reviewed and recorded by the service.

In the 12 months prior to the inspection 15 of the 17 written compliments received were from MRI patients.

Outstanding practice and areas for improvement

Outstanding practice

- The provider had an open sided MRI scanner which allowed patients who could not tolerate a conventional scan because they were obese or suffered from claustrophobia to be scanned.

Areas for improvement

Action the provider MUST take to improve

- The provider must have a risk register covering corporate risks and risks to patients are identified, assessed and monitored consistently on each scan appointment, and that action plans and assessments are updated and contain enough detail to enable staff to reduce those risks effectively.

Action the provider SHOULD take to improve

- The service should have a system in place to ensure all MRI safety records and Gadolinium contrast consent forms are signed by radiographers.
- The service should have a system to identify, record, review and report incidents.
- The service should have a system to ensure all polices, procedure and guidance documents are reviewed, are current and are in date.
- The service should have a system in place to confirm all staff have read existing, updated or new polices, procedure and guidance documents.
- The service should have a fire evacuation record test book**.**
- The service should have a business continuity plan.
- The service should have a documented lone working policy or agreement.

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 12 HSCA (RA) Regulations 2014 Safe care and treatment Regulation 12 HSCA 2008 (Regulated Activities) Regulations 2014 Safe care and treatment. (a) assessing the risks to the health and safety of service users of receiving the care or treatment; (b) doing all that is reasonably practicable to mitigate any such risks; The provider did not have a risk register covering either corporate or patient risks. There was no system in place to review risk and identify themes or to develop mitigation strategies. Risk was not discussed at the quarterly management meetings.

Regulated activity	Regulation
Diagnostic and screening procedures	Regulation 17 HSCA (RA) Regulations 2014 Good governance Regulation 17: Good governance 17 (2) Without limiting paragraph (1), such systems or processes must enable the registered person to; (a) assess, monitor and improve the quality and safety of the services provided in the carrying on of the regulated activity (including the quality of the experience of service users in receiving those services); (b) assess, monitor and mitigate the risks relating to the health, safety and welfare of service users and others who may be at risk which arise from the carrying on of the regulated activity;

This section is primarily information for the provider

Requirement notices

(f) evaluate and improve their practice in respect of the processing of the information referred to in sub-paragraphs above.

21 out of 22 provider policies, procedures and guidance documents were found to be out of date.

The providers mission statement and philosophy of care statement was not displayed on any notice boards or on the services internet site and staff were not aware of it.

The provider did not have a risk register and risk was not discussed at the quarterly management meetings. Performance information was not evaluated to improve performance.

The provider did not have a business continuity plan.