Lady McAdden Breast Screening Unit

Quality Report

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

Ratings

Overall rating for this location	Good
Are services safe?	Good
Are services effective?	
Are services caring?	Good
Are services responsive?	Good
Are services well-led?	Requires improvement

Overall summary

Lady McAdden Breast Screening Unit is operated by Lady McAdden Breast Screening Trust. The service offers routine screening by mammography, consultation for clinical examination and breast awareness and osteoporosis clinics run at a location nearby. The service has one mammography x-ray room, two clinical rooms, waiting areas and administration areas.

The service offers routine mammography (aged 40 years and over), ultrasound examination, breast examination and awareness advice and osteoporosis clinics for patients aged 18 years and over. Patients self-refer to the service which is funded solely by charitable donations.

Summary of findings

We inspected this service using our comprehensive inspection methodology. We carried out the announced part of the inspection on 12 December 2018, with a further visit to the service on 7 January 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.

The main service provided by this hospital was routine mammography screening using diagnostic imaging equipment (x-ray).

Services we rate

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

We found the following areas of good practice:

- Staff understood how to protect vulnerable patients from abuse.
- Diagnostic imaging equipment had been regularly maintained in line with manufacturers recommendations.
- The service controlled infection risk well. Staff kept themselves, equipment and premises clean. Control measures were in place to prevent and control the spread of infection.
- The service had enough staff.
- Medical records were complete, contemporaneous, well organised and secure.
- Staff of different kinds worked together as a team to benefit patients.
- Staff cared for patients with compassion and provided support to minimise distress.
- Staff involved patients and those close to them in decisions about their care.
- The service planned and provided services to meet the needs of local people whilst mostly taking account of individual need.
- Patients could access the service in a timely manner.
- The service treated concerns and complaints seriously and sought patient feedback through a variety of methods.
- The service had a clear mission statement in place with workable plans to turn it in to action.
- Managers across the service promoted a positive culture that supported and valued staff.
- The service engaged well with patients, staff and the public.
- Staff offered a bespoke service and were committed to improving services by forward planning the future delivery of breast awareness education and mammography to self-referring patients.

We found the following areas the service needs to improve:

- We could not gain assurances that staff directly employed by the service had completed mandatory training at recommended intervals.
- Protocols did not contain reference to national guidance.
- We were unable to gain assurances that the service managed incidents (including those relating to patient safety) in an effective manner. There was no incident reporting policy in place.
- The service had limited systems in place to identify, monitor and regularly review risk.

Following this inspection, we told the provider that it must take some actions to comply with the regulations and that it should make other improvements, even though a regulation had not been breached, to help the service improve. We also issued the provider with one requirement notice that affected diagnostic and screening services. Details are at the end of the report.

Amanda Stanford

Deputy Chief Inspector of Hospitals

Summary of findings

Our judgements about each of the main services

Service	Rating	Summary of each main service
Diagnostic imaging	Good	The service is a registered charity and offers routine mammography screening, clinical examinations, breast awareness education and osteoporosis clinics. In diagnostic imaging services we found the following areas of good practice: The service effectively prevented and controlled the spread of infection. Medical records were complete, contemporaneous and well organised. The service was responsive to the needs of local people whilst treating patients on an individual basis. Staff described an open culture and reported feeling valued in their role. However, we also found that: There were limited systems and processes in place to oversee and ensure compliance with mandatory training including (safeguarding training). We could not gain assurances that the service managed incidents well; there was no incident reporting policy in place. The service had limited systems in place to identify, monitor and regularly review risk.

Summary of findings

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Good

Lady McAdden Breast Screening Unit

Services we looked at
Diagnostic imaging

Summary of this inspection

Background to Lady McAdden Breast Screening Unit

Lady McAdden Breast Screening Unit is operated by Lady McAdden Breast Screening Trust. The Trust was founded in 1968 with the service subsequently opening in May 1976. The service offers routine mammography (aged 40 years and over), ultrasound examination, breast examination and awareness advice and osteoporosis clinics for patients aged 18 years and over. Patients self-refer to the service which is funded solely by charitable donations.

Our inspection team

The team that inspected the service comprised a CQC lead inspector and one other CQC inspector. The inspection team was overseen by Fiona Allinson, Head of Hospital Inspection.

Information about Lady McAdden Breast Screening Unit

Lady McAdden is a charity funded organisation which offers breast screening services for women in the aim of the early detection of breast cancer. Other services offered include breast awareness education and osteoporosis clinics, delivered from purpose built premises.

The service is registered to provide the following regulated activities:

- Diagnostic and screening procedures.

During the inspection, we visited the unit's location in Southend-on-Sea, Essex. We spoke with four staff including registered radiographers, reception staff, and senior managers. We spoke with two patients. During our inspection, we reviewed 12 sets of patient records.

There were no special reviews or investigations of the hospital ongoing by the CQC at any time during the 12 months before this inspection. The service has been inspected twice, and the most recent inspection took place in October 2013 which found that the service was meeting all standards of quality and safety it was inspected against.

Activity (December 2017 to November 2018)

- In the reporting period, the service saw 2977 patients for breast mammography, 439 for osteoporosis screening and 925 for other clinical examinations and breast awareness/education consultations. All patient care is funded through charity and voluntary donations.

Two consultant radiologists, three clinic sisters (registered nurses), an assistant practitioner (with advanced skills in mammography) and regular agency radiographers worked at the service. In addition, a number of staff were employed with responsibilities for reception duties, finance, fundraising and administrative roles. The service did not use controlled drugs and therefore there was no accountable officer for controlled drugs (CDs) in place.

Track record on safety (15 October 2017 to 15 October 2018)

- No never events
- No serious incidents
- No ionising Radiation Medical Exposure Regulations reportable incidents (IRMER)
- No ionising Radiation Regulations reportable incidents (IRR)
- Clinical incidents zero no harm, zero low harm, zero moderate harm, zero severe harm, zero death
- No serious injuries

Summary of this inspection

No incidences of hospital acquired Meticillin-resistant Staphylococcus aureus (MRSA),

No incidences of hospital acquired Meticillin-sensitive staphylococcus aureus (MSSA)

No incidences of hospital acquired Clostridium difficile (c.diff)

No incidences of hospital acquired E-Coli

One complaint (not upheld)

Services provided at the hospital under service level agreement:

- Provision of radiation protection and advice and medical physics quality assurance and expert services.

Summary of this inspection

The five questions we ask about services and what we found

We always ask the following five questions of services.

Are services safe?

Good

We rated safe as **Good** because:

- Staff understood how to protect vulnerable patients from abuse.
- Diagnostic imaging equipment had been regularly maintained in line with manufacturers recommendations.
- The service controlled infection risk well.
- The service had enough staff.

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

- We were unable to gain assurances that the serviced managed patient safety incidents well. There was no incident reporting policy in place.
- Systems and processes to monitor staff's compliance with mandatory training (including safeguarding) were not embedded.

Are services effective?

We did not rate effective however we found the following areas of good practice:

- Staff monitored the effectiveness of imaging in relation to the diagnosis of breast cancer.
- Staff from various roles worked well together, to benefit patients.
- Staff understood how and when to assess whether a patient had capacity to make decisions about their care.

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

- Protocols did not contain reference to national guidance.

Are services caring?

Good

We rated caring as **Good** because:

- Staff cared for patients with compassion and kindness.
- Staff provided emotional support to patients to minimise distress.
- Patients and those close to them were involved regarding decisions about their care.

Summary of this inspection

Are services responsive?

Good

We rated responsive as **Good** because:

- The service planned and provided services in a way that met the needs of local people.
- The service mostly took account of a patient's individual needs.
- Patients could access the service in a timely manner.
- The service treated concerns and complaints seriously, with guidance for staff in place.
- The service welcomed patient feedback through a variety of methods.

Are services well-led?

Requires improvement

We rated well-led as **Requires improvement** because:

- The service had limited systems in place to identify, monitor and regularly review risk.
- At the time of our inspection, there were ineffective systems and processes in place to ensure staff compliance with mandatory training.

However, we also found the following areas of good practice:

- The service had a mission for what it wanted to achieve and workable plans to turn it in to action.
- Managers across the service promoted a positive culture that supported and valued staff.
- The service engaged well with patients, staff and the public to plan and manage appropriate services.

Detailed findings from this inspection

Overview of ratings

Our ratings for this location are:

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

Good

Diagnostic imaging

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

Are diagnostic imaging services safe?

Good

We rated safe as **good.**

Mandatory training

- **The service provided a programme of mandatory training in key skills to all staff directly employed by the service. However, on the day of our inspection, we were unable to gain assurances that all staff directly employed by the service had completed training at recommended intervals.**
- Staff employed directly by the service had access to online mandatory training in a number of subjects including, but not limited to; fire safety and information governance. However, at the time of our inspection there were no effective systems and processes in place to monitor and oversee compliance with mandatory training for staff directly employed by the service.
- Staff completed mandatory training during normal working hours however the registered manager could not provide records of dates staff had completed training. Therefore, we were unable to gain assurances that staff had completed mandatory training at recommended intervals.
- We raised our concerns at the time of our inspection and the registered manager advised they would try and obtain compliance data from the online learning system (for staff who were directly employed by the service).
- Agency radiographers and consultant radiologists held substantive posts with NHS organisations. The registered manager reported overseeing their compliance with mandatory training through the provision of agency information. However, agency documentation did not detail specific mandatory training subjects covered or specific dates for training completion. We could not gain assurance that there were effective systems and processes in place to ensure staff had received mandatory training at regular and recommended intervals. However, after our first inspection, the registered manager forwarded evidence that agency radiographers had completed and were up to date with mandatory training courses.
- Agency staff's mandatory training courses included but were not limited to; fire safety, information governance, conflict resolution, moving and handling, risk incident reporting and infection prevention and control.
- For remaining staff who were directly employed by the service, the registered manager had imposed a completion deadline of 19 January 2019 for staff to complete the required training.This was part of the registered manager's new plan to ensure that future compliance was overseen on a regular basis and therefore ensure that staff had completed all required training.
- At our second inspection on 7 January 2019, we discussed progress with staff's completion with mandatory training. We saw progress had been made for clinical staff who were on track with the deadline of 19 January 2019 for completion.
- The registered manager told us that in the future, staff were to attend two mandatory training days to ensure

that compliance with mandatory training was maintained and regularly overseen. In the future, dedicated days in December would be put aside to ensure training took place at regular intervals as part of the new plan to oversee compliance with mandatory training.

Safeguarding

- **Staff understood how to protect patients from abuse and the service had access to other agencies (local authorities) to report suspected or actual abuse. Radiographers had received training on how to recognise and report abuse. However, we could not gain assurances that staff directly employed by the service had received safeguarding adults and children training due to a lack of effective systems and processes in place to monitor compliance.**
- There had been no reported safeguarding concerns in the 12 months prior to our inspection.
- The registered manager was the safeguarding lead for the service and had completed safeguarding adults level three training in May 2018.
- The safeguarding children and young people; role and competences for health care staff intercollegiate document (March 2014) outlines minimum recommended safeguarding training requirements for those working in health care related services.
- We could not gain assurances that all staff directly employed by the service had received and were up to date with safeguarding adults and children training (both clinical and non-clinical staff) in line with national guidance.
- This was not in line with the intercollegiate document which states reception staff should complete safeguarding children training level one. The document states that nursing staff, working in an adult setting, should have completed level two safeguarding children training. Whilst the service did not see or examine patients under 18 years of age, on occasions, children may have accompanied patients to the service.
- The service was unable to provide evidence that reception, clinical and non-clinical staff had completed this training. However, staff were clear on how to raise concerns and the adult safeguarding policy was within review date and contained instructions on how to identify and raise safeguarding concerns, with onward referral to the relevant local authority if required.
- The safeguarding policy did not contain guidance or reference to female genital mutilation or government's PREVENT strategy. The aim of this strategy is to provide staff with the knowledge to enable them to be aware of the need to safeguard vulnerable people from being drawn into terrorism or exploited for extremist behaviour.
- However, the service had identified the lack of safeguarding training as a risk. In response to this and prior to our unannounced inspection, the registered manager had put a plan in place to ensure that staff received appropriate training which had been booked for the month following our inspection. We saw evidence that staff were due to complete this pre-booked training.
- Posters detailing potential signs of abuse were on display to help guide staff, along with key contact number to the local authority.
- The service had leaflets within waiting areas providing information to patients and visitors on safeguarding from abuse.
- We raised our concerns regarding the lack of safeguarding adults and children training with the registered manager on the day of our inspection. They advised that safeguarding training for staff had been planned to take place the month following our inspection.
- Information provided after our inspection demonstrated that all staff were due to attend a pre-booked (prior to our inspection) safeguarding adults and children training session in the month following our inspection (8 January 2019). In addition, we saw evidence of training certificates indicating that agency radiographers had completed adult and child safeguarding training, levels one and two.

Good

Diagnostic imaging

- There was no specific chaperone policy in place. The service employed only female mammographers, therefore all patients were examined by a member of the same sex.
- During consultations with a consultant radiologist, all patients were examined in the presence of a female clinic sister. Patients were welcomed to take relatives and carers in to examinations and consultations if they so wished.
- Staff were subject to disclosure and barring service (DBS) checks prior to the commencement of employment. We reviewed staff files and saw DBS certificates for all members of staff.
- Radiographers carried out 'pause and check' checking processes prior to radiation exposure. Checks included the patients name, date of birth and address, confirmation of pregnancy status, date of last mammogram (if applicable), and also ensured the patient had read information on procedure to be carried out. We saw these checks being carried out on the day of our inspection.

Cleanliness, infection control and hygiene

- **The service controlled infection risk well. Staff kept themselves, equipment and premises clean. They used control measures to prevent the spread of infection.**
- There were effective processes in place to prevent and control the spread of infection.
- All areas we inspected appeared clean and free from visible dirt.
- Cleaning services were outsourced to a third-party company. Cleaning took place three days per week, with checklists in use for cleaning in between each patient and at the end of each clinical session.
- We reviewed quarterly environmental cleanliness audits which demonstrated 100% compliance for the months of June 2018 and September 2018. The registered manager and clinic staff regularly checked environmental cleanliness in all areas.
- All flooring and seating was wipe clean to enable effective cleaning. Surface disinfectant wipes were available throughout clinical areas.
- All clinical areas were hard floored to enable effective cleaning.
- There was clear segregation of clinical and non-clinical waste. The service did not use sharps (needles) and therefore did not require clinical waste sharps bins.
- Hand cleansing gel was available at regular intervals throughout the service, however, there was no visible information for staff or patients in relation to the five moments of hand hygiene. The five moments of hand hygiene are guidelines to indicate when healthcare professionals should perform hand hygiene practices.
- From 15 October 2017 to 15 October 2018, the service had no reported cases of Meticillin Resistant Staphylococcus Aureus (MRSA), Meticillin Sensitive Staphylococcus Aureus (MSSA), Escherichia coli (E-Coli) or Clostridium difficile (C-diff).
- The service had an infection prevention and control (IPC) lead in post. An IPC policy was available for staff and was due for review in February 2019. The policy detailed cleaning processes, schedules and staff responsibilities to ensure equipment and environmental cleanliness.
- All staff in clinical areas had arms bare below the elbow to help prevent and control the spread of infection.
- At the time of our inspection we could not gain assurances that agency staff had received training in infection prevention and control as training records were not available. Following our inspection, the service submitted evidence that both agency radiographers had received training in infection prevention and control (level two).

Environment and equipment

- **The service had suitable premises and equipment and mostly looked after them well.**
- There were mostly effective systems and processes in place to maintain equipment within the service.
- The service was located within a purpose-built building in the grounds of an NHS hospital site.

Good

Diagnostic imaging

- Access to the unit was restricted to authorised personnel only to ensure the safety of staff and patients at all times. At all times during our inspection, access to the unit was restricted and by buzzer entry only.
- The service was located on the first floor and contained offices, a reception and waiting area, film reporting room, two clinical rooms and private waiting area.
- Access to clinical and non-clinical areas was restricted to non-authorised personnel.
- Rooms where radiation exposure took place were clearly marked with warning signs and lights. Unauthorised access was restricted. We saw warning signs and lights in use on the day of our inspection, all areas were monitored and had oversight from reception staff.
- Lead screens were in place to protect staff from radiation. These were checked on a regular basis by the service's medical physics expert.
- Lead aprons were available for use if required and were subject to regular integrity checks by the service's medical physics expert.
- The service maintained an information folder detailing all substances that may be hazardous to health. This was in line with the Control of Substances Hazardous to Health Regulations 2002 (COSHH).
- Staff working within areas exposed to radiation wore dosimeters. A dosimeter is a device that measures exposure to ionising radiation. Dosimeters analysis and replacement took place on a three-monthly basis with results being overseen by the service's medical physics expert.
- We checked two fire extinguishers within the waiting area and found both were due for maintenance in July 2017. We raised our concerns to the registered manager at the time of our inspection.
- Following our inspection, the service provided information which indicated all fire extinguishers had been serviced and were covered under an existing maintenance contract. At our second inspection on 7 January 2019, we saw all fire extinguishers had been replaced in line with the existing maintenance contract in place.
- We found that electrical equipment within office areas has passed its recommended date for electrical testing. We raised our concerns with the registered manager who assured us that this would be addressed as a matter of urgency.
- The service used one mammography machine and one ultrasound machine at the location. We reviewed servicing records and saw both had received a service at recommended intervals.
- The digital mammography machine had a backup power supply in place. This enabled the completion of each image in the event of mains failure.
- Routine quality assurance (QA) testing of equipment took place, records which we reviewed from October 2018 showed QA testing had taken place on the equipment in use within recommended timeframes. Equipment tested included, but was not limited to; monitors, the mammography system and electrical warning lights and signals. This was in line with the ionising radiation regulations 2017 (IRR17).

Assessing and responding to patient risk

- **Staff completed and updated risk assessments for each patient. They kept clear records and asked for support when necessary.**
- All patients received an assessment prior to mammography to ensure suitability for examination and to prevent over exposure from radiation.
- Due to the nature of services provided, the service did not have an emergency resuscitation trolley. No medicines were used at the service. A first aid trained member of staff was available at all times during service opening hours.
- In the event of medical emergency, staff were clear that the first aider was called and an emergency ambulance requested if necessary.
- Agency radiographers had received training in basic life support and resuscitation to respond to patient collapse and cardiac arrest if required.

Good

Diagnostic imaging

- Both agency radiographers had received training in conflict resolution to provide skills in dealing with the complex and varied situations and behaviour.
- There were clear processes in place to refer patients with abnormal mammography or ultrasound findings. Referral letters were sent to the local breast unit on the same day if an anomaly was discovered.
- All mammography images were reported on by both consultant radiologists who worked at the service. This was in line with The Royal College of Radiologists 'screening and symptomatic breast imaging' guidance. We reviewed 12 medical records which demonstrated both consultant radiologists had viewed all images.
- Arrangements were in place to receive and view previous diagnostic images from nearby local hospitals. This ensured that patients did not receive unnecessary exposure to radiation. A document named 'requesting images from other units' provided staff with guidance on how to request images and contact details for other organisations. The document was in date and due for review in January 2019.
- The service had a radiation protection advisor (RPA) and medical physics expert (MPE) supplied through a service level agreement (SLA). We reviewed the SLA and noted it was in date.
- All staff described the RPA and MPE as responsive and contactable at all times.
- The service had a nominated radiation protection supervisor in post.
- Clear signage was in place to warn patients of areas where radiation exposure took place therefore preventing unrestricted access.
- Each clinical area contained an emergency alarm cord in the event of emergency or patient collapse.
- The service had copies of the local ionising radiation rules available at regular locations throughout the service. Local rules were in place to ensure the health and safety of patients and staff in areas where ionising radiation was in use. Details of the RPS and RPA were included in the local rules, which was in line with The Ionising Radiations Regulations 2017 (IRR 17).
- We saw the local rules were regularly reviewed with next review planned to take place in August 2019. This was in accordance with the Ionising Radiation Regulations (IRR).
- Staff signed to acknowledge reading of the local rules. We saw evidence that 11 out of 12 staff had read this document.
- Staff had access to a medical physics expert in the event of advice being required regarding diagnostic reference levels (DRLs). DRLs are a tool to optimise levels of radiation.
- Pregnancy status was routinely checked prior to any imaging taking place.

Radiographers and Nurse staffing

- **The service had enough staff with the right qualifications, skills, training and experience to keep people safe from avoidable harm and to provide the right care and treatment.**
- Staffing levels were planned and reviewed in advance to ensure that an adequate number of suitably trained staff were available for each clinic.
- The service employed three part-time clinic sisters for the provision of breast awareness, advice and education consultations. Clinic sisters also supported consultant radiologists during consultations and whilst ultrasound examinations were carried out.
- Agency radiographers were in place to carry out mammography consultations. The service used two regular agency radiographers for all clinics, with support from the registered manager who was also trained to carry out mammograms.
- The service had set minimum staffing requirements for all sessions. This included one receptionist, a clinic sister and radiographer. This meant there were suitably skilled and qualified staff available at all times.
- The service used agency staff when required. In the three months prior to 15 October 2018, 89 shifts had been carried out by agency staff.

Good

Diagnostic imaging

- The service had one vacancy for a part time radiographer. This post had been out to advert however recruitment was unsuccessful. The registered manager told us they were considering re-advertising in early 2019 to try and recruit to this post.
- Prior to commencement of work, all agency staff were shown around the unit, shown local protocols and relevant safety regulation information. The agency member of staff was supported by a regular staff member to ensure they were confident and competent in their role.
- The service had a lone working policy in place, which was in date and provided guidance to staff on processes where lone working occasions might occur, for example locking and unlocking premises.

Medical staffing

- The service used two consultant radiologists who worked alternative weeks at the location to provide consultations, carry out ultrasound examinations and report on mammogram images. Both consultant radiologists held substantive roles in NHS organisations.
- The service did not use agency medical staffing.
- When not in clinic, consultant radiologists were available for advice, if required by a radiographer.
- One clinic ran at a time and the consultant radiologist's attendance was planned in advance.
- Consultant radiologists always had a clinic sister present during all consultations and examinations.

Records

- **Staff kept records of patients' care and examinations. Records were clear, up-to-date and easily available to all staff providing care.**
- Medical records were paper based, with the reporting of images held electronically and printed for storage in patient files.
- Images were held electronically and if required, sent to the local breast unit on an encrypted disk. The service sent all passwords separately to ensure confidentiality of records.
- We reviewed medical records for 12 patients. All records demonstrated patient identifiable details on each insert, were well organised and stored within a secure area at the service.
- Medical records were audited on a regular basis. Audit areas included but were not limited to; date of attendance, identification checks, consent, exposure recording, radiographer signature and that reporting had taken place by both consultant radiologists. For the last three months of data prior to our inspection, compliance with the medical records audit was 100% for all months.
- The service offered osteoporosis scanning clinics at a nearby location. The registered manager told us this site was not used for the storage of medical records and all information was returned to the unit after each clinic. At the time of our inspection, the osteoporosis service was not in operation due to staff sickness.
- All records were checked for quality assurance purposes by a clinic sister to ensure both radiologists had completed the reporting process and that all records were signed. Results were then entered on to a computer to enable results to be sent to patients.
- Medical records demonstrated onward referral to the NHS (where applicable). Referrals to the NHS were sent to the local breast unit. We reviewed two medical records and saw that onward referral had taken place within six working days (after dual reporting from both consultant radiologists).
- Clinic staff monitored completion of referral processes through use of a paper document, attached to the front of medical records. This ensured that patients received referral and follow up appointments in a timely manner.
- A document named 'retention of records' guided staff on the length of retention for medical records. The document had been reviewed and provided clear guidance to staff on the storage, retention periods and destruction of medical records.

Medicines

- The service did not stock or administrator medicines as they were not required in this setting or for the type of services offered.

Good

Diagnostic imaging

Incidents

- **We were unable to gain assurance that the service managed patient safety incidents well.**
- The service had no incident reporting policy in place, however, incident reporting was covered during staff induction.
- The duty of candour is a regulatory duty that relates to openness and transparency and requires providers of health and social care services to notify patients (or other relevant persons) of 'certain notifiable safety incidents' and provide reasonable support to that person. However, we found no documents to provide guidance to staff on the duty of candour.
- The registered manager advised that if required, incidents would be reviewed at regular trust board meetings which took place on a bi-monthly basis.
- There had been one non-clinical incident in the 12 months prior to our inspection. We reviewed the incident report and noted that appropriate action had been taken at the time of this incident.
- Staff used a specific form to record and report radiation doses greater than the intended dose. The service had a named radiation protection advisor (RPA) who oversaw incidents relating to radiation. There had been no radiation incidents in the 12 months prior to our inspection.
- At our second inspection on 7 January 2019, the registered manager advised they were in the process of compiling a draft incident reporting policy, to ensure staff had access to guidance in the event of an incident occurring. In addition, a staff handbook was being written which when complete, would also contain guidance on incident reporting processes within the service.

Are diagnostic imaging services effective?

We did not rate effective in diagnostic imaging.

Evidence-based care and treatment

- Local protocols were reviewed on a regular basis. We reviewed protocols and saw that the last reviews had taken place in November 2018, overseen by consultant radiologists who both held substantive posts in external NHS organisations. However, protocols did not contain documented reference to national guidance. At our second unannounced inspection on 7 January 2019, the registered manager discussed progress was being made with regards to our concerns and that a review of documentation was taking place, to ensure reference to key guidance including; NHS public health functions agreement 2018-19 and the NHS Breast Screening Programme, December 2017.
- The service used diagnostic reference levels (DRLs, a tool for optimising levels of radiation) as an aid to optimisation in medical exposure. The service used a digital machine with pre-set DRLs, however, protocols were in place to guide staff when adjusted DRLs were required, for example when x-raying a patient with breast implants.
- The medical physics expert (MPE) audited DRLs on a regular basis and in addition, a three-yearly audit was carried out. The next audit was due to take place in 2020. Staff contacted the service's MPE in the event of DRLs falling outside of normal range.

Nutrition and hydration

- Due to the nature of service provided, food was not routinely offered. However, the service offered fresh drinking water within waiting areas and hot drinks could be provided if required.

Pain relief

- **Staff monitored patients regularly to assess if they were in pain during mammogram procedures. We saw that staff frequently checked a patient's comfort levels during examination.**
- Due to the nature of services provided, pain relief was not required during examination and consultation.

Patient outcomes

- **Managers and clinical staff monitored the effectiveness of imaging in relation to the diagnosis of breast cancer. Due to the bespoke nature of service provided, it was not possible to compare local results with those of other services to learn from them.**

Good

Diagnostic imaging

- The service monitored patient outcomes and completed annual reports to the local NHS trust. This enabled the service to monitor how many patients had been diagnosed with breast cancer through the provision of mammography examination for self-referring patients.
- The service did not participate in national audits due to the nature of service provided.

Competent staff

- **The service made sure that staff were competent for their roles.**
- Staff were provided with an initial face to face induction which included but was not limited to; clinic familiarisation, review of local protocols and policies.
- Both consultant radiologists and agency radiographers were employed in substantive roles with external NHS trusts.
- The registered manager checked that relevant staff had up to date registration in place (nursing and midwifery council and health and care professions council).
- The registered manager demonstrated evidence of both consultant radiologist appraisals (with their substantive NHS trusts) having taken place in the 12 months prior to our inspection.
- In addition, the registered manager held annual checks for consultant radiologists to ensure there were no restrictions on practice from the NHS roles at which they worked.
- We reviewed seven staff files. Out of these, four staff had received an appraisal in the 12 months prior to our inspection. The registered manager was in the process of recruiting a new operations director, to commence in post in early 2019 and explained that the appraisal process would form part of the new operations manager's role.

Multidisciplinary working

- **Staff of different kinds worked together as a team to benefit patients.**
- Staff communicated with each other on a regular basis. Informal meetings took place with consultant radiologists on a weekly basis however these were not documented.
- We saw evidence of effective multi-disciplinary working with communications between the service and other NHS breast care providers and GPs.
- The service had systems and processes in place to communicate and refer to the local NHS breast unit in the event of further examination and or treatment being required. We saw evidence to other healthcare professional took place in a timely manner.

Seven-day services

- The service opened Monday to Friday, with varying opening hours of 9am-5pm Tuesday, Wednesday and Thursday, 11am-7.30pm on Mondays and 9am to 1pm on Fridays. This enabled the service to offer a range of appointments times to suit patient needs.
- In addition, the service provided additional clinics on Saturdays when there was an increased demand for appointments.

Health promotion

- Service's offered included breast imaging (mammography), breast awareness education consultations and osteoporosis screening. This empowered patients to learn how to monitor their own health through the self-checking of their breasts.
- The service provided a range of information to patients and visitors on a number of health-related subjects including but not limited to; domestic violence, osteoporosis, breast cancer and smoking cessation.
- Patients had access to information on breast awareness, examination, ultrasound, mammography and osteoporosis screening services.

Consent and Mental Capacity Act

- **Staff understood how and when to assess whether a patient had the capacity to make decisions about their care. They followed the service policy and procedures when a patient could not give consent.**

Good

Diagnostic imaging

- We reviewed 12 medical records which demonstrated that written documented consent was obtained prior to examination.
- Staff had access to a consent policy providing guidance on obtaining consent and the Mental Capacity Act 2005.
- All staff we spoke with were clear in their responsibilities in the obtaining and documentation of consent.
- Clinic sisters assessed a patient's understanding of mammogram procedures at first consultation. If a patient was unable to understand and co-operate with mammogram procedures, referral back to their GP took place.

Are diagnostic imaging services caring?

Good

We rated caring as **good.**

Compassionate care

- **Staff cared for patients with compassion. Feedback from patients confirmed that staff treated them well and with kindness.**
- Patient feedback was consistently positive. We reviewed a number of comments cards received during November 2018. All comments were positive and included; 'friendly, helpful and caring', couldn't be more helpful', 'wonderful place' and 'expert professional and caring'.
- Throughout the duration of our first day of inspection, we saw all staff greeted patients in a warm and welcoming manner, clearly explaining to patients what to expect during their consultation.
- Patients we spoke with described staff as caring and kind.
- Patient who had been recalled for discussion of examination findings were supported in private consultation areas to respect privacy and dignity.

Emotional support

- **Staff provided emotional support to patients to minimise their distress.**
- Relatives and carers were welcomed to attend consultations with their loved ones (except for when ionising radiation was in use).
- In the event of a patient anxiety, relatives or carers could enter the room providing they were behind protective lead screens to ensure unnecessary exposure to radiation.
- The service welcomed calls for advice should patients have any queries around breast awareness education and mammography procedures.
- The service did not offer counselling services and referred requests for such care to the patient's GP to ensure access to specialist support, if required.

Understanding and involvement of patients and those close to them

- **Staff involved patients and those close to them in decisions about their care.**
- At initial consultation, staff discussed preferred contact methods with patients for investigation results. Patients could choose to receive results either by email or letter, and were advised this process took approximately three weeks.
- Patients were advised they could contact the unit at any point for further advice, if required.
- The service provided a wide range of information on its website relating to consultations, mammograms, osteoporosis screening and what patients could expect during their appointment.
- Staff respected patients' privacy and dignity. Reception areas played background music to ensure that private conversations could not be overheard. In addition, sensitive discussions took place in private areas.

Good

Diagnostic imaging

Are diagnostic imaging services responsive?

Good

We rated responsive as **good.**

Service delivery to meet the needs of local people

- **The service planned and provided services in a way that met the needs of local people.**
- The service was planned and delivered to meet the needs of local people and offered flexibility in appointments times, including Saturday clinics during periods of increased demand to ensure patients were seen in a timely manner.
- The service offered a range of care including mammograms, breast awareness education and osteoporosis screening.
- The premises and facility were appropriate for the delivery of service.
- The service was centrally located in the grounds of an NHS hospital with onsite parking. In addition, local public transport links were available.
- There were adequate seating areas within the service, it was well lit and provided access to drinking water. Waiting areas were designed to provide a calm environment to make the patient visit as relaxing as possible.
- A lift was available to facilitate ease of access to patients with additional mobility needs. The service and all areas within the service were accessible to wheelchairs users.
- The service worked with local NHS breast units to ensure that referral, if required took place to the patient's hospital of choice.
- The service provided was bespoke; no other service within the area offered routine mammography screening to patients aged 40 and over.

Meeting people's individual needs

- **The service mostly took account of patients' individual needs.**
- A suggested donation amount was discussed with patients at the point of booking, however, the service placed emphasis on welcoming patients without compulsory donations and recognised patients on an individual basis.
- The service offered a range of appointment times and where possible, facilitated short notice appointments.
- The department did not have access to translation services and relied on relatives or carers in the event the patient's first language was not English. Therefore, we could not gain assurances that patients, whose first language was not English, had access to all information during examination and consultation.
- Whilst staff did not receive specific chaperone training, all staff we spoke with told us they would facilitate chaperones at a patient's request. In addition, all ultrasound clinics were run with one consultant radiologist and one clinic sister. The registered manager (trained in mammography), was present at all times during clinic opening hours and was therefore available to chaperone if required. In addition, a clinic sister was on site to provide a chaperone role if required.
- If required, double length appointments were booked to ensure patients had adequate time to discuss any concerns or test results.
- The service offered a range of examinations including breast imaging (mammography), breast awareness education consultations and osteoporosis screening. This meant the service could offer a range of consultations, to suit individual patient need.
- The service assessed patients with learning disabilities on an individual basis. A written procedure was in place to provide guidance for staff on the consultation and examination of patients with learning disabilities. All patients were seen and assessed by the clinic sister prior to mammography taking place to ensure suitability for imaging.
- Lift access ensured those with additional mobility needs could access the service, located on the first floor.
- Disabled toilet facilities were available.

Good

Diagnostic imaging

- The service's public website provided guidance on how to contact the service should a patient have a query or need advice through a call back service.

Access and flow

- **People could access the service when they needed it. Due to the bespoke nature of service provided, there were no national recommended waiting times.**
- The service offered access to consultations and mammogram screening in a timely manner, providing appointments for self-referring patients only. Breast education and awareness consultations were offered to patients aged 18 years and over with annual routine mammography for patients aged 40 years plus and bi-annual recalls for patients aged 50 years and over.
- The service booked appointments up to three weeks in advance. Waiting times were monitored by the registered manager with additional clinics added where demand required.
- The service monitored how patients accessed the service, for example; friends and family recommendations or through direction from their GP. The registered manager monitored this data which showed that in the two months prior to our inspection, the majority of patients came to the service after recommendation from friends or a family member.
- We saw that the service was responsive to additional demand for appointments through the provision of five additional clinics in January 2019.
- Rates of those who did not attend (DNA) were documented and monitored by the registered manager. Staff contacted all patients that DNA to ensure a new appointment was booked in a timely manner.
- Upon receipt of an appointment request, staff took a brief history. If there was any indication of anomaly, for example a suspected breast lump, the service directed patients to their GP for referral on the appropriate NHS pathway.
- Patients could also request an appointment via the service's public website.
- We spoke with one patient who had been visiting the service for over 20 years. They told us they had always received an appointment in a timely manner and that clinics ran on time.
- On the day of our inspection, we saw that all patients were seen in a timely manner, at intended appointment times.

Learning from complaints and concerns

- **The service treated concerns and complaints seriously and sought patient feedback through a variety of methods.**
- The service had a complaints procedure document in place to guide patients on how to make a complaint. The document had been reviewed in February 2018.
- The service had received one complaint in the 12 months prior to our inspection. This was a verbal complaint which was resolved in a timely manner at the time of the complaint being received.
- Staff sought feedback through a variety of methods. Information on complaints was available on the service's website. In addition, patient comments cards were placed in visible areas to seek feedback to drive service improvements.

Are diagnostic imaging services well-led?

Requires improvement

We rated well-led as **requires improvement.**

Leadership

- **Managers at the service mostly had the right skills and abilities to run a service providing high-quality sustainable care.**
- The service had a clear leadership structure in place. The management team consisted of a business manager, finance manager and lead clinician.
- The clinic sisters, agency radiographers and non-clinical staff reported to the business manager. The manager was an experienced healthcare professional and had worked at the service for a number of years. After commencing work in an

administrative role at the service, the registered manager completed further training to include mammography and also gaining managerial experience and responsibilities.

- During our inspection, we saw the business manager was visible, supportive and engaged with all clinical and non-clinical staff and had an 'open door' policy in place to encourage staff communication.
- The service's business manager was in the process of registering for a 'level five management course' to further develop skills within their role.
- The registered manager and board of trustees recognised the challenges the service faced due to being solely funded through charitable and voluntary donations, with actions in place to continue fundraising to ensure sustainability of the service in the future.

Vision and strategy

- **The service had a mission for what it wanted to achieve and workable plans to turn it in to action. The mission had been developed in conjunction with staff and those who used the service.**
- Staff were passionate about providing high quality and safe, patient focussed care.
- The service's mission statement was: 'At Lady McAdden we aim to offer services for the early detection of breast cancer. Through mammography screening from age 40 and education in breast awareness we provide health promotion, advice, education and support for women of any age. This service is offered by professional and caring staff who have the time and experience to care'. The service's vision was displayed in waiting areas.
- The service had clear core values which were: respect for the individual offering equal opportunities, care empathy, a community centred approach and health promotion. However, due to no provision of translation services we could not gain assurances that equal opportunities were being provided for all patients.
- During our inspection, we saw examples of where staff were empathetic, supportive and caring when interacting with patients.
- The service was bespoke, in that it offered routine mammography screening to patients aged 40 to 47 years of age. It had been previously identified that this was an age range that was not routinely scanned through the provision of NHS services.

Culture

- **Managers across the service promoted a positive culture that supported and valued staff, creating a sense of common purpose based on shared values.**
- Staff were consistently positive when describing the culture within the service. They felt supported by all leaders and colleagues within the service.
- During our inspection we saw that staff interacted and engaged with each other in a polite, positive and supportive manner.
- Staff reported feeling supported by the service's business manager, describing them as 'nice, accessible and supportive'.

Governance

- The service was overseen through trustee board meetings. The unit manager and finance manager fed in to the board on a regular basis and had input with regards to agenda items.
- Board of trustee meetings took place on a bi-monthly basis. We saw that meetings were attended by a broad range of staff.
- We reviewed meeting minutes from November 2018 which demonstrated staff (consultant radiologist) review of clinical protocols in use.
- Informal weekly staff meetings took place between clinical staff (nursing staff and consultant radiologists) however, we were unable to review contents of discussions as these were not minuted.
- Staff at all levels were clear in their roles and responsibilities.
- The service regularly informally reviewed reporting times and added additional clinics, where required to cope with increased demand.

Good

Diagnostic imaging

- We saw evidence that the service level agreement for the provision of radiation protection and advice and medical physics quality assurance and expert services was in date and regularly reviewed.
- In approximately June 2018, the registered manager had identified that a number of policies were awaiting update. The registered manager described how actions had been put in place to ensure that policy updates took place on a regular basis through sign off from the trust board. A number of other polices we reviewed, including but not limited to; equality and grievance processes, were in date and had been reviewed on a regular basis.
- The registered manager requested disclosure and barring service (DBS) checks for all members of staff. We saw that all staff had received a DBS check prior to the commencement of work at the service.

Managing risks, issues and performance

- **The service had limited systems in place to identify, monitor and regularly review risk.**
- The Board of trustees took overall responsibility for oversight of risk within the service.
- The service had a risk management policy in place. We reviewed this document, which was marked as 'draft' and due for review in June 2018, six months prior to our inspection.
- Risk management was a standing agenda item and bi-monthly trustee meetings. Meetings were attended by a broad range of staff.
- We reviewed meeting minutes from July 2018 and September 2018 and saw there was limited discussion of risk the service may face. Meeting minutes from November 2018 discussed plans to implement more risk management documentation and further review of risks to the service, however we were unable to see evidence this had taken place due to the timing of our inspection
- We reviewed the services risk assessment which documented risks including but not limited to; manual handling, fire, infection prevention control and equipment. We saw documentation lacked regular review dates and actions.
- We raised our concerns with the registered manager. At our second inspection on 7 January 2019, we saw that the document had been amended to ensure it detailed who was responsible for each risk, actions taken and dates for completion. In addition, the registered manager had implemented monthly meetings with the service lead sister, to discuss and review risk on a regular basis.
- The new monthly risk assessment meetings were due to be fed back to board meetings to ensure all staff within in the service had knowledge of the risks and challenges the service may have faced.
- Whilst some clinical staff worked at other NHS organisations, there was no documentary evidence in place to ensure all staff had received mandatory training and safeguarding training at recommended intervals. We raised our concerns with the unit's manager at the time of inspection who advised they gained assurance of this through the agencies supplying the radiographers. However, at the time of our initial inspection, there was a lack of oversight in place for staff directly employed by the service.
- At our second inspection, we saw the registered manager had put plans in place to oversee and monitor staffs' compliance with mandatory training completion on a regular basis.
- The service had a business plan in place for the period of 2017-2019. The business plan covered a variety of subjects, including but not limited to; service demand, performance, and opportunities.

Managing information

- Regular discussion took place around appointment waiting times and clinic demand.

Engagement

- **The service engaged well with patients, staff, the public and other local organisations to plan and manage appropriate services.**
- The service engaged with the local population through a variety of methods including; social media, local news and a public website. All platforms provided a range of information to people on the services offered and breast education/awareness consultations.

Good

Diagnostic imaging

- The service gathered the views of patients through use of patient feedback systems.
- Although not documented, staff met on a regular basis to discuss service delivery and planning. Meetings were attended by the registered manager.

Learning, continuous improvement, sustainability and innovation

- **The service was committed to improving services by forward planning the future delivery of breast awareness education and mammography services to self-referring patients.**
- The service had previously secured new premises to ensure that care could continue to be provided when the service's current lease expired (due in 2024). Action plans had been submitted to the board in early November 2018 to ensure funds for premises adaptations and equipment purchase were in place.
- Staff were dedicated in fundraising efforts and used a variety of methods to raise money to ensure that the service was sustainable and accessible to all. Volunteer staff dedicated time to support the service in continued fundraising efforts to ensure sustainability of the service and increasing income.

Outstanding practice and areas for improvement

Outstanding practice

- The service provided was bespoke and supported all patients, irrespective of voluntary financial contributions.
- The service was open to all patients over the age of 18, with no age limit for breast awareness and education consultations. In addition, the service offered routine mammograms to patients aged 40 years and over on a self-referral basis.

Areas for improvement

Action the provider MUST take to improve

- The provider must ensure that risks to the service are regularly reviewed and documented.

Action the provider SHOULD take to improve

- The provider should ensure that there are systems and processes in place to enable staff to understand and apply the duty of candour, if required.
- The service should ensure that systems or processes are in place to provide access to translation services for patients whose first language is not English.
- The service should ensure the systems and processes in place to monitor equipment maintenance are embedded.
- The service should ensure that the systems and processes in place to monitor mandatory training (including safeguarding adults and children) are effective and embedded.

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 17 HSCA (RA) Regulations 2014 Good governance **The service had limited systems in place to identify, monitor and regularly review risk.**