The Harley Street Breast 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	Good
Are services safe?	Good
Are services effective?	
Are services caring?	Good
Are services responsive?	Good
Are services well-led?	Good

Overall summary

The Harley Street Breast Clinic is a private breast screening and diagnostic service based in central London. The service offers a single speciality which accepts patients on a referral or walk-in basis. The service is owned and operated by UniLabs Ltd, and was registered with the CQC in October 2010. The Harley Street Breast Clinic provides a one stop clinic where patients have a consultation and diagnostic tests, with results provided to the patient usually on the same day.

Diagnostic tests provided by the service include ultrasound, mammogram, and biopsy. The service also has a walk-in or referral breast screening service for women over the age of 40. Staff at the service included breast surgeons, mammographers, radiographers, registered nurses, and healthcare assistants.

Services we rate

We rated it as good overall.

Summary of findings

- The service environment was clean and well maintained.
- There were comprehensive infection prevention and control processes.
- The service had enough staff, with the right mix of qualification and skills, to keep patients safe and provide the right care and treatment.
- Staff completed and updated risk assessments for each patient. Patient records were clear, up-to-date and easily available to all staff providing care.
- The service managed patient safety incidents well. Staff recognised incidents and reported them appropriately, and any incidents were investigated thoroughly.
- The service provided care and treatment based on national guidance and evidence of its effectiveness.
- Managers monitored the effectiveness of care and treatment and used the findings to improve them.
- The service made sure staff were competent for their roles.
- Doctors, nurses and other healthcare professionals supported each other to provide good care.
- Staff cared for patients with compassion. Feedback from patients confirmed that staff treated them well and with kindness.
- During this inspection we saw all staff treating patients with dignity, kindness, compassion, courtesy and respect.
- Staff provided reassurance and support for patients throughout their appointment.
- The service had a strong person-centred culture. Staff were motivated and inspired to offer care that was kind and reflected the individual needs of each patient.
- Patents we spoke with were happy with reporting times. Diagnostic reports were usually available on the same day
- Patients were offered a choice of appointment times. Patients we spoke with told us they were given appointment times that suited them.
- The service had an agreement with a translation phone service to provide access to an interpreter if needed.
- The provider's website provided useful information about the service, staff, procedures that were provided, and the referral process.
- The service had a clear management structure.
- Staff told us the registered manager and clinical director were approachable and supportive, and that they could reach them when needed.
- Staff were positive and happy in their role and stated the service was a good place to work. Staff told us they felt supported, respected and valued by the management.
- There was a robust corporate and local governance framework in place which oversaw service delivery and quality of care.

However:

- Referral forms did not provide guidance on referral criteria or space for information about complex needs.
- The service incident and complaints policy did not include information on duty of candour.
- The service did not collect or analyse information relating to waiting times, missed appointments, or cancellations.
- The service did not have a specific vision or strategy document.

Summary of findings

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Summary of this inspection

Background to The Harley Street Breast Clinic

The Harley Street Breast Clinic is a private breast screening and diagnostic service based in central London. The service offers a single speciality which accepts patients on a referral or walk-in basis. The service is owned and operated by UniLabs Ltd, and was registered with the CQC in October 2010.

The Harley Street Breast Clinic provides a one stop clinic where patients have a consultation and diagnostic tests, with results provided to the patient usually on the same day. Diagnostic tests provided by the service include ultrasound, mammogram, and biopsy. The service also has a walk-in or referral breast screening service for women over the age of 40.

Staff at the service included Consultant Breast Surgeons, registered nurses, and healthcare assistants. The register manager has been in post since 2014.

The service outsourced the radiation protection advisers (RPA) and medical physics experts (MPE) to a nearby NHS trust, as well as maintenance of ultrasound and mammography machines.

Patients can self-refer, or may be referred by another healthcare professional. The service operates an appointment and a walk-in service with no appointment required between 9am and 5pm.

Our inspection team

The team that inspected the service comprised a CQC lead inspector and a specialist advisor with expertise in diagnostic imaging. The inspection team was overseen by Terri Salt, Head of Hospital Inspection.

Information about The Harley Street Breast Clinic

The service is registered to provide the following regulated activities:

- Diagnostic and screening

During the inspection, we visited the service location on Harley Street. This consisted of a consultation room, two diagnostic rooms, one labratory, reception and waiting areas, and office space. The service was located on the third floor of a shared building.

We spoke with five staff members including consultant surgeons, the registered manager (and senior mammographer), nursing staff, healthcare assistants, and administrative staff. We spoke with three patients and reviewed five sets of electronic patient 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. The service was last inspected in 2013, which found that the service was meeting all standards of quality and safety it was inspected against.

Activity (November 2017 to November 2018):

- The service sees approximately 200 patient visits per month, with a split of approximately 35% screening mammogram appointments and 65% one stop (consultation) visits.

Track record on safety:

- There were no never events, serious incidents/injuries in the last 12 months.
- There were no Ionising Radiation (Medical Exposure) Regulations (IR(ME)R) reportable incidents in the last 12 months.
- There were no hospital-acquired infections in the last 12 months.

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:

- The service environment was clean and well maintained.
- There were comprehensive infection prevention and control processes in place.
- The service had enough staff, with the right mix of qualification and skills, to keep patients safe and provide the right care and treatment.
- Staff completed and updated risk assessments for each patient.
- Patient records were clear, up-to-date and easily available to all staff providing care.
- The service provided mandatory training in key skills to all staff and made sure everyone completed it.
- The service managed patient safety incidents well. Staff recognised incidents and reported them appropriately, and any incidents were investigated thoroughly.

However:

- Referral forms did not provide guidance on referral criteria or space for information about complex needs.
- The service incident and complaints policy did not include information on duty of candour.

Are services effective?

We do no rate effective, however we found:

- The service provided care and treatment based on national guidance and evidence of its effectiveness.
- The provider's policies and procedures were subject to review by the radiation protection advisor (RPA) and the medical physics expert (MPE), in line with IR(ME)R 2017 requirements.
- Managers monitored the effectiveness of care and treatment and used the findings to improve them.
- The service made sure staff were competent for their roles.
- Doctors, nurses and other healthcare professionals supported each other to provide good care.

Are services caring?

Good

We rated caring as good because:

- Staff cared for patients with compassion. Feedback from patients confirmed that staff treated them well and with kindness.

Summary of this inspection

- During this inspection we saw all staff treating patients with dignity, kindness, compassion, courtesy and respect.
- Patients were contacted on a yearly basis in November to complete feedback questionnaires, and the service collated this feedback to inform changes to service delivery.
- Staff provided reassurance and support for patients throughout their appointment.
- The service had a strong patient-centred culture. Staff were motivated and inspired to offer care that was kind and reflected the individual needs of each patient.

Are services responsive?

Good

We rated responsive as good because:

- Patents we spoke with were happy with reporting times. Diagnostic reports were usually available on the same day.
- Patients could choose an appointment times that best suited them.
- The service had an agreement with a translation phone service to provide access to an interpreter if needed.
- The service's multidisciplinary team (MDT) policy stated that other professionals involved in patient's care would be involved in MDT meetings where there were co-morbidities or complex needs.
- The provider's website provided useful information about the service, staff, procedures that were provided, and the referral process.

However:

- The service did not collect or analyse data relating to waiting times, missed appointments, or cancellations.

Are services well-led?

Good

We rated Well-led as good because:

- The service had a clear management structure.
- Staff told us the registered manager and clinical director were approachable and supportive, and that they could reach them when needed.
- Staff were very positive and happy in their role and stated the service was a good place to work.
- Staff told us they felt supported, respected and valued by the management.
- There was a robust corporate and local governance framework in place which oversaw service delivery and quality of care.

Summary of this inspection

- The service collected, analysed, managed and used information well to support all its activities, using secure electronic systems with security safeguards.

However:

- The service did not have a specific vision or strategy document.

Detailed findings from this inspection

Overview of ratings

Our ratings for this location are:

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

Good

Diagnostic imaging

Safe	Good
Effective	
Caring	Good
Responsive	Good
Well-led	Good

Are outpatients and diagnostic imaging services safe?

Good

We rated this service as good.

Mandatory training

- **The service provided mandatory training in key skills to all staff and made sure everyone completed it.**
- All staff were required to complete mandatory training or provide evidence that it had been completed at another service. The service provided training directly to nursing staff and healthcare assistants through a third party provider, while consultants completed training at another service and shared the certificate.
- Training from the third party provider was a mix of classroom delivered training and e-learning. Staff stated they felt this worked well.
- The mandatory training courses included resuscitation training, infection control, fire safety, information governance, safeguarding adults and children (both level two), moving and handling, conflict resolution, and information governance.
- Evidence provided by the service after the inspection showed 100% of both nursing and medical staff had completed required mandatory training and were up to date.
- Compliance for mandatory training was monitored by the service manager via a spreadsheet. Staff stated they were responsible for ensuring their training was up to date, and this was reviewed in annual appraisals.

Safeguarding

- **Staff understood how to protect patients from abuse and the service worked well with other agencies to do so.** Staff had training on how to recognise and report abuse and they knew how to apply it.
- The service manager was the designated safeguarding lead for the service, and staff stated they would approach the manager if they had any safeguarding concerns. The service did not have any safeguarding incidents since the last inspection.
- All staff had completed safeguarding adult levels one and two training. The registered manager had completed safeguarding level three training. Staff had a good understanding of when they would need to report a safeguarding concern.
- At inspection the staff had not completed the safeguarding children levels one and two training. Staff had informed us that children under 18 would often visit the service with their families, and may wait with staff while their parents went to their appointment. This meant that staff did not have the training to recognise safeguarding concerns for children who attended the service. Following inspection the service provided evidence that staff had completed the safeguarding children levels one and two training.
- We reviewed the service's safeguarding policy, this detailed what to do in the event of a safeguarding concern and reflected the service's obligations under safeguarding legislation. Staff were required to sign and date that they had read the policy.
- The service had an up to date chaperone policy. All staff received training in chaperoning and were available for any patient requiring this.

Cleanliness, infection control and hygiene

Good

Diagnostic imaging

- **The service controlled infection risk well.** Staff kept equipment and the premises clean. They used control measures to prevent the spread of infection.
- There had been no incidents of health care acquired infection in the service during the reporting period.
- The service provided staff with personal protective equipment (PPE) such as gloves and aprons. Staff told us they wore PPE where necessary. We observed all staff adhered to the 'bare below the elbows' protocol in clinical areas.
- Staff used a cleaning schedule with post-clinic, weekly, and monthly tasks to be completed. We observed these tasks being carried out, such as deep cleaning after clinic had ended for the day, and signed as completed.
- Hand-washing facilities were available for staff in the clinical areas. Posters prompting appropriate hand washing technique were displayed on doors, but were not displayed in front of sinks. The service completed hand hygiene checks as part of the annual infection prevention and control (IPC) audit, and identified good practice. We also observed good hand hygiene from staff in clinical areas.
- The service conducted a bi-monthly health and safety audit which included examination of IPC practices. The service also had an annual IPC audit completed by an external health and safety advisor, and the report required response to any areas of non-compliance within three months. The last annual IPC report was completed in November 2018, and identified good compliance with IPC practices.
- The service had an up to date infection control policy and we observed good compliance in relation to the policy. This policy was updated regularly to reflect best practice, and staff were required to sign they had read the policy.
- Waste was separated and disposed of in line with best practice guidance relating to clinical waste and sharps. As part of the induction checklist, staff were informed of local arrangements relating to clinical waste disposal, and sharps.
- The service had a suitable control of substances hazardous to health (COSHH) policy and procedures in place for staff to follow. COSHH risk assessments were undertaken, and the service ensured compliance with COSHH arrangements through the annual IPC audit.

Environment and equipment

- **The service had suitable premises and equipment and looked after them well.**
- The layout of the unit was compatible with health and building notification (HBN06) guidance for facilities for diagnostic imaging and interventional radiology.
- Concerns regarding the building environment were reported to the building manager. Staff told us there were usually no problems or delays in getting repairs completed quickly.
- The diagnostic machines were serviced as part of a planned maintenance programme which ensured equipment met Ionising Radiation (Medical Exposure) Regulations (IR(ME)R) requirements and any breakdown of equipment was addressed quickly. We observed the equipment maintenance logs and found them to be up to date.
- Failures in equipment and medical devices were reported to the practice manager and action was taken promptly. Between November 2017 and November 2018, the service had 15 appointments delayed due to breakdown of equipment, however staff stated that these issues were rectified quickly and appointments were able to proceed later or be re-booked.
- We reviewed the equipment used in the management of patients in a medical emergency. The service had a pocket mask and defibrillator, as well as an epinephrine injector for allergic reactions, but did not have any medicines for use in the event of a medical emergency. The equipment was checked regularly. The service had a policy for medical emergencies which stated staff should call 999 and perform Cardiopulmonary resuscitation (CPR) until the ambulance arrives. The service had not had any incidents of patients deteriorating and requiring emergency care.
- The service had a health and safety statement which detailed the arrangements and meetings for monitoring and controlling environmental risks. Environmental risks were audited in the bi-monthly health and safety check.
- We reviewed the Radiation Protection Adviser (RPA) report in 2018 for service equipment and the radiation output testing results showed all equipment were safe for use. In addition, the reports concluded all equipment was in good working condition.
- There was suitable signage showing the room was a controlled area for radiation. The controlled light sign in

front of the rooms turned on automatically when the diagnostic rooms were in operation, as a safety warning. During procedures staff used protective screens to observe x-rays and scans.
- To monitor staff exposure to radiation, the RPA conducted a bi-annual check of radiation levels in various areas throughout the service, which was reviewed and monitored.
- Staff informed us the automatic calibration of equipment occurred every morning and we saw that staff completed daily checklist which highlighted equipment had been calibrated.
- The main reception area on the ground floor was clean and welcoming. The waiting rooms on the third floor had adequate seating and space in for the number of patients attending clinics, with access to toilet facilities for visitors.

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.
- Staff assessed and managed patient risk in accordance with national guidance. Risks were managed proactively, clinical risk assessments (such as blood pressure) were carried out in appointments, and information was updated appropriately in the patient records.
- The referral form for the service included space for additional clinical information to be provided, such as last menstrual period, symptoms and family history. However, the form did not include information on referral criteria or encourage referrers to inform the service of any potential complex needs. This meant that referrals may leave some vital information out of the referral that could improve the individual delivery of care to a patient.
- All clinical staff had received resuscitation training as part of their mandatory training. The induction checklist for new staff included knowing the location of the first aid kit, pocket masks, and defibrillator for use in the event of an emergency.
- There was a comprehensive risk assessment in place in line with the application of the IR(ME)R guidance in 2017 to operate medical X-ray equipment. The risk assessment covered protection measures for staff involved in radiography and people outside the clinical rooms, dose assessment and investigations, maintenance, and quality assurance.
- The unit had access to a radiation protection advisor (RPA) and a medical physics expert (MPE). This service was provided by a London NHS trust, and the RPA provided an annual audit of compliance with IR(ME)R guidelines. The registered manager for the service fulfilled the role of the Radiation Protection Supervisor (RPS) in compliance with the IR(ME)R requirements.
- There were exposure protocols and diagnostic reference levels (DRLs) in place. These were available in both diagnostic rooms and pasted on walls. DRLs were set by the RPA and audited every six months.
- The service had an up-to-date fire evacuation plan. A fire risk assessment had been undertaken in November 2018 and there was an action plan in place. Staff undertook fire safety training as part of their mandatory courses. We also saw evidence of the fire safety arrangements being discussed in the service health and safety meeting minutes,
- The service complied with the Society and College of Radiographers (SCOR) guidance on a "pause and check" process of confirmation of patient information and examination before proceeding with the assessment. This process aimed to minimise the risk of incorrect action during the examination, or an unintended or overexposure of radiation. The service displayed posters for the pause and check process in clinical areas, and we observed staff complying with the guidance.
- The service ensured that staff checked if patients may be pregnant prior to the patient being exposed to radiation, in accordance with IR(ME)R guidance. We saw this check reflected in the patient records.

Medical staffing

- **The service had enough medical staff, with the right mix of qualification and skills, to keep patients safe and provide the right care and treatment.**
- Medical leadership consisted of a clinical director, while consultants breast surgeons and radiologists working with the service were employed under practising privileges. Prospective and existing practising privileges were reviewed by the medical advisory committee (MAC).

- Medical staff ran a weekly clinic where patients could specifically request an appointment with their preferred consultant or select the next available appointment.
- Medical staff were required to complete mandatory training to ensure competencies were up to date. Medical staff undertook their training with another service they primarily worked with and evidence of completion to this service. Medical staff were also required to provide evidence of maintaining their professional registration.
- The service had not used any vacancies in medical staffing and did not use locums within the last twelve months.

Radiography and Nursing staffing

- **The service had enough nursing staff, with the right mix of qualification and skills, to keep patients safe and 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 did not have any current vacancies.
- The service employed one part-time nurse and a part-time healthcare assistant for the provision of supporting diagnostic tests alongside the senior mammographer, radiologists, and consultant surgeons. The registered manager was also trained to carry out mammograms.
- The service used bank radiography cover when the senior mammographer was unavailable, as they had not suitable bank candidates for mammography. Between October 2018 and November 2018, the service had one agency shift to cover the mammographer.
- Any agency or bank staff received a site induction which was documented on a checklist and signed off. This included fire safety and emergency procedures, clinic layout, diagnostic processes, local rules for radiation safety, first aid contact, PPE use, and equipment specific training.
- The agency staff always worked alongside permanent members of the team for continuity. Agency shifts would be arranged by an agency approved by Unilabs. The service manager stated that gaps in the rota would be identified well in advance and agency cover could be arranged.
- Mammographers and nursing staff were required to attend annual mandatory training, as well as to maintain their specialist registration and professional development activities. Nursing staff stated they were supported to do this, and compliance was reviewed in their annual appraisal.
- Nursing staff stated they felt supported in their roles by their manager.

Records

- **Staff kept detailed records of patients' care and treatment.** Records were clear, up-to-date and easily available to all staff providing care.
- Patient records were stored on an electronic system. We looked at a random sample of five electronic patient records and found them to be well completed. All records had details of the patient, the healthcare professional referring them, as well as any previous appointments or scans the patient may have had with the service.
- All patient's data, medical records and scan results were documented via the service's secure patient system. Electronic records could only be accessed by authorised personnel. We observed good practice in relation to ensuring patient information was treated confidentially and securely.
- The service had a process for reporting incidents relating to breaches of information governance. The IT reporting policy clearly outlined the process, including informing IT services, and if necessary the Caldicott Guardian.

Medicines

- **The service followed best practice when prescribing, giving, recording and storing medicines.** Patients received the right medication at the right dose at the right time.
- The service held, prescribed and administered a limited range of pain relief medicines following mammograms or biopsies. We found medicines to be stored securely within their recommended temperature ranges, and the administration of medicines recorded in both the patient records and in the log of medications.
- Medicines reconciliation was also recorded every week, and we found this to be completed accurately. The service did not use patient group directions (PGDs) and also did not store or administer any controlled drugs.

Incidents

Good

Diagnostic imaging

- **The service managed patient safety incidents well.** Staff recognised incidents and reported them appropriately. Managers investigated incidents and shared lessons learned with the whole team and the wider service. When things went wrong, staff apologised and gave patients honest information and suitable support.
- Between November 2017 to November 2018 there had been no serious incidents requiring investigation, as defined by the NHSI Serious Incident Framework 2015. Serious incidents are events in healthcare where the potential for learning is so great, or the consequences to patients, families and carers, staff or organisations are so significant, that they warrant using additional resources to mount a comprehensive investigation.
- There had been no 'never events' in the previous 12 months prior to this inspection. Never events are serious incidents that are entirely preventable as guidance, or safety recommendations providing strong systemic protective barriers, are available at a national level, and should have been implemented by all healthcare providers.
- There had been no notifiable safety incidents that met the requirements of the duty of candour regulation in the 12 months preceding this inspection. 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.
- Staff were aware of the principles of duty of candour and when it would be applied. Duty of candour formed part of the mandatory training modules. Staff also stated they felt encouraged to report incidents if they identified concerns.
- The service had an incident policy which the staff followed when investigating incidents. However, neither the incident policy or the complaints policy mentioned the service's requirement to be open and transparent with patients when there had been an incident. The policy also did not outline a procedure by which patients would be involved in the investigation process.
- Incidents or complaints to the service were investigated by the service manager and the MAC. We reviewed incidents reports and minutes from the MAC from the last twelve months and found them to be comprehensively investigated and reviewed.
- Staff also were aware of incidents that had occurred within the service and felt they had been learning from them. Staff stated they were informed of incidents and leaning through team meetings and emails.

Are outpatients and diagnostic imaging services effective?

We do not rate the effective domain.

Evidence-based care and treatment

- **The service provided care and treatment based on national guidance and evidence of its effectiveness. Managers checked to make sure staff followed guidance.**
- Care and treatment was delivered to patients in line with National Institute for Health and Care Excellence (NICE) and Royal Colleges guidelines. Staff told us they followed national and local guidelines and standards to ensure effective and safe care. National best practice was reflected in the policies we reviewed.
- Staff assessed patients' needs and planned and delivered patient care in line with evidence-based, guidance, standards and best practice.
- Staff had access to the service's policies and guidelines via a shared folder. Paper copies of local protocols and policies were also available to staff. All protocols and guidelines we reviewed were in date, and staff were required to sign that they had read them.
- The service carried out several clinical audits to ensure care was delivered in line with their policies and with national guidance. For example, the service performed an average glandular dose (AGD) audit every six months, which ensured patients were receiving safe levels of exposure to radiation.
- The provider's policies and procedures were subject to review by the radiation protection advisor (RPA) and the medical physics expert, in line with IR(ME)R 2017 requirements. The service applied the Public Health England guidance on National Diagnostic Reference Levels when setting their local DRLs. Compliance with DRLs and IR(ME)R requirements was monitored by a London NHS trust through a service level agreement, who completed an annual audit. There was also a programme of local audits in place to monitor radiation safety.

- The service completed an annual review of procedures and protocols (last completed in February 2019) to ensure processes complied with best practice and national legislation. We saw evidence of this review updating to comply with IR(ME)R guidelines.

Nutrition and hydration

- **Patients had access to hot and cold drinks while attending the service.**
- Patients had access to water and hot drinks in the waiting area whilst awaiting their appointment. During our inspection we saw patients helping themselves to drinks in the main waiting rooms.

Pain relief

- **Staff assessed and monitored patients regularly to see if they were in pain.** Staff supported those unable to communicate using suitable assessment tools and gave additional pain relief to ease pain.
- The service did not hold any controlled drugs. There were some minor painkillers available on request for patient that experienced discomfort following mammogram or biopsy, and this was recorded in the patient records.
- We reviewed pain medication and found it was stored securely and recorded correctly in the medicine log and in patient records.

Patient outcomes

- **Managers monitored the effectiveness of care and treatment and used the findings to improve them.**
- The service conducted several local audits in order to evaluate the quality of care being received by patients. The results were reviewed by the MAC to discuss possible changes to service delivery.
- In June 2018, the service completed an audit to assess the success of the biopsy procedure at the service under a number of outcomes. The results found in 55 biopsies performed during the reporting period (June 2016 to May 2017), there was only one that resulted in the procedure being terminated early due to bleeding. This patient was then followed up closely with other diagnostic procedures.
- The service was audited by the RPA on an annual basis to ensure safe practice in relation to patient safety and IR(ME)R requirements. The most recent annual audit in March 2018 stated that the service was fully compliant with no improvements required, and that equipment was maintained and procedures carried out to a high standard.
- All mammograms were double reported by two consultant breast radiologists, one from the service and another colleague available remotely with access to the imaging system. If there was a disagreement between the reports of consultants, this was sent for arbitration (a third read) and the event is logged along with the patient hospital number. This information is then provided to the radiology lead for analysis and reviewed during the next MAC meeting for learning.
- The service required all imaging and diagnostic reports were sent to the consultant breast surgeon and/or to the referring doctor. Any concerns about the quality of reports were raised and investigated as an incident which followed the service's incident reporting guidelines.

Competent staff

- **The service made sure staff were competent for their roles.** Managers appraised staff's work performance and held supervision meetings with them to provide support and monitor the effectiveness of the service.
- All staff received a local and corporate induction. Staff completed an induction and competency checklist when they first started which covered use of equipment, using the service's systems, departmental understanding, and clinical competency skills relevant to their job role and experience.
- Staff received an annual appraisal as part of their roles, which included review of performance as well as plans for professional development. Staff stated they found the appraisals useful, and data provided by the service show that all staff had received an appraisal in the past 12 months.
- The service had a practicing privileges policy, and surgeons and radiologists working for the service under the policy. Practicing privileges were granted at the discretion of the Medical Advisory Committee (MAC) and practising surgeons were required to provide assurance around their training and continued competency. Minutes from the MAC also showed attendance from practising surgeons and radiologists.

Diagnostic imaging

- All staff were required to complete a mandatory training programme paid for by the service, or provide evidence that they had completed this training with another provider. Evidence showed that mandatory training was monitored by the registered manager.
- Staff were required to provide evidence of their registration with the regulated body of their profession. We saw evidence of staff registration with the Health and Care Professions Council (HCPC), General Medical Council (GMC), and the Nursing and Midwifery Council (NMC). Staff were required as part of their employment to ensure they retained their registration and revalidated when it came close to expiry.
- Staff told us they had good access to training regarding their professional development. Staff could identify areas for developmental and stated they were supported by managers to attend training and conferences.

Multidisciplinary working

- **Staff of different disciplines worked together as a team to benefit patients.** Doctors, nurses and other healthcare professionals supported each other to provide good care.
- The service provided a one-stop screening service which included the input of radiologists, consultants, nursing staff, and mammographers. This meant the patient could access a comprehensive examination from a multidisciplinary team in a relatively short appointment time.
- Staff stated they had good working relationship as a team and across disciplines. Staff stated they worked well together collaboratively and this was supported by an effective and approachable manager.
- Staff stated they had a good working relationship with external partners. For example, the service often worked collaboratively with another provider including the other service providing specialist staff, such as breast care nurses, for specific patients.
- The service had a local policy for multidisciplinary **(**MDT) working, which included procedure on how joint working should be carried out. The policy also included a section on including other healthcare professionals involved in the care of complex patients.
- Evidence from the MAC showed that radiologist attended the meetings along with consultants, the managing director for the organisation, and the registered manager.

Health promotion

- **Staff advised patients on about their health choices and how to improve lifestyle factors**
- Information leaflets were provided in the waiting areas and online for patients on what the scan would entail and what was expected of patients prior to a scan. The service had produced their own leaflets to explain mammograms, ultrasounds, and biopsies to patients. The service also provided information to patients on self-care following a scan, which included wound care following biopsy.
- During diagnostic imaging, the clinic staff signposted patients to the NHS website for information on reducing breast cancer risk. Patients were signposted to a breast cancer charity website for information.
- Staff stated that consultants would discuss with patients about their health choices and how to improve lifestyle factors to reduce risk of cancer (smoking cessation and reducing weight etc.)

Consent, mental capacity act and deprivation of liberty safeguards

- **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.
- Patients gave consent prior to an intervention. Consent was recorded in the patient record and signed by both patient and consultants. The service had also developed specific consent forms for stereotactic biopsy and mammograms for patients with breast implants, which provided information and expected outcomes on the procedures, as these examinations may involve additional discomfort.
- In December 2018 the service completed an audit of consent forms by selecting five records for review. The review showed that consent had been recorded in all five of the cases examined.
- There was a process to ensure verbal consent was gained before an intervention commenced. We observed good practice in relation to patients being

informed of the procedure and staff checking that patients were comfortable before proceeding. Patients were also provided with sufficient time to ask any questions before they had their procedures.
- The service had a policy regarding consent, which staff were required to read and sign that they had done so. The policy reinforced that staff must understand the legality around consent, patients refusing consent, and the Mental Capacity Act.
- Staff understood their roles and responsibilities in obtaining consent and their responsibilities under the Mental Capacity Act 2005.

Are outpatients and diagnostic imaging services caring?

Good

We rated this service as good.

Compassionate care

- **Staff cared for patients with compassion. Feedback from patients confirmed that staff treated them well and with kindness.**
- During this inspection we saw all staff treating patients with dignity, kindness, compassion, courtesy and respect. In each interaction we saw staff explained their roles, the purpose of the patient's visit, and put patients at ease during their consultation and diagnostic tests.
- We spoke with three patients during the inspection. Patients spoke positively about the quality of care they had received and how they were treated during their appointment. Patients told us they did not feel rushed, that staff were respectful of their time, and they were given enough time to ask questions at any stage. Patients stated the staff were professional, and they were impressed that the consultant and mammographer at their appointments were well informed of their treatment history.
- Staff welcomed patients when they arrived at the reception and at the main entrance to the service and introduced themselves. We observed the consultants greeting the patients in the reception area before taking them into the consultation room.
- Senior staff informed us they operated a provider wide "Care Big" philosophy to ensure patients were treated with respect, were made to feel at ease, and that they had as much choice as possible in their care. All staff were aware of this approach to care, and the service manager was a provider wide ambassador for the philosophy.
- Patients were contacted annually in November to complete feedback questionnaires, and the service collated this feedback to inform changes to service delivery. The service manager collected thank you cards from patients and shared them with staff. Messages we saw included: "The staff are fantastic, extremely professional, and instil confidence", "I am so grateful for you fitting me in for an appointment at short notice", and "Thank you for making my appointment so stress free".
- The service had completed a patient satisfaction survey in November 2018 for one-stop, screening, and biopsy patients and received 55 responses. The results showed that 98% of patients would recommend the service to friends, 95% found the consultant/mammographer explained the procedures clearly, 92% found the clinic room clean and 92% were given adequate information and kept informed throughout their visit. However, only 38% of screening patients and 20% of one stop patients stated they were aware of how to make a complaint.

Emotional support

- **Staff provided emotional support to patients to minimise their distress**.
- Staff understood the impact that patients' care, treatment and condition had on wellbeing. Staff stressed the importance of treating patients as individuals and this was reflected in the interactions we observed.
- Staff provided reassurance and support for nervous and anxious patients throughout their appointment. Staff were all trained in how to chaperone patients and demonstrated a calm and reassuring attitude so as not to increase anxiety for nervous patients.
- The service had two waiting rooms so if patients were receiving difficult news, this could be done in one of the waiting rooms in private, without the patient needing to return to the other waiting room while awaiting the results.
- The service did not employ a breast care nurse as part of the service, however they did have a positive working relationship with a senior breast care nurse at the location where most patients would have treatment

following diagnosis. Staff stated the breast care nurse was available to visit the service and could provide information to patients who may be receiving a difficult diagnosis.
- Patients were given time to ask questions after their scan and staff provided clear the required information in a way that was easy to understand.

Understanding and involvement of patients and those close to them

- **Staff involved patients and those close to them in decisions about their care and treatment.**
- The service had a strong patient-centred culture. Staff were motivated and inspired to offer care that was kind and reflected the individual needs of each patient.
- Staff communicated with patients so they fully understood their care and treatment options. Patients were actively involved in their care, and this was reflected in the patient records we reviewed.
- Patients reported feeling involved in the decision making and understood what they were attending the service for, the types of investigations they were having, and what to expect after the appointment. Patients told us staff communicated well with them, and answered any questions they had.
- Staff recognised when relatives and carers needed to be involved in the patients care and treatment. Staff stated they could provide information for family members if needed, and family members or carers could accompany the patient for their appointment. We observed family members attending appointments with patients.
- Staff recognised when patients or relatives and carers needed additional support to help them understand and be involved in their care and treatment. Staff enabled them to access this, including access to interpreting and translation services.

Are outpatients and diagnostic imaging services responsive?

Good

We rated this service as good.

Service delivery to meet the needs of local people/ Planning and delivering services which meet people's needs

- **The service planned and provided services in a way that met the needs of local people.**
- The one stop breast clinic provided consultation and diagnosis for patients over 18 with a concern of breast cancer. Patients had all tests on one day and received their result from a consultant breast surgeon on the same day. The breast screening service provides women over the age of 40 access to mammographic breast screening without the need for referral. The mammograms were double read by two consultant breast radiologists. The results were sent to the patient and their elected GP or referrer.
- The service provided planned diagnostic treatment for patients on referral or for walk-in mammogram patients, normally in the London area but also accepted referrals from national and international patients.
- The provider's website provided useful information about the service, staff, procedures that were provided, fees, and the referral process. The website also contained information about different types of breast disease and the treatments available.
- We observed that patients were seen promptly and patients could book the next available appointment (depending on if they had a preference of consultant). Staff told us patients were seen promptly and there were no waiting lists, although the service did not collect information on waiting times.
- The service was located on the third floor of a day surgery unit. Patients and visitors to the service could access via a staircase. Patients with limited mobility could use the lift access, however this was a small elevator. Staff stated they could offer appointments at another location with improved access if needed. The unit operated a walk-in service between 9am and 5pm Monday to Friday.
- The environment of the service was appropriate and patient-centred. The waiting and consultation rooms were comfortable and welcoming, and there were toilet facilities for patients and visitors.
- Patients were provided with appropriate information about their visit including an explanation of procedures, frequently asked questions, information on breast screening from Public Health England, and directions to the waiting area of the service.

- The service provided payment details in a confirmation email prior to each patient's attendance. These included a clear price list and different options for payment. Our review of electronic patient records included confirmation emails sent to patients and this confirmed the price for the procedure.

Meeting people's individual needs

- **The service took account of patients' individual needs.**
- Visitors had access to a tea and coffee machine and water in the waiting areas. They also had access to magazines and information about the service.
- The service's multidisciplinary (MDT) policy stated that other professionals involved in patient's care would be involved in MDT meetings where there were co-morbidities or complex needs. Staff stated they would follow this process if they had patients with additional needs.
- The referral form for the service did not include space for referrals to provide additional information on the patients' needs. Staff stated any co-morbidities or complex needs would be discussed over the phone with referrer.
- The service had managed patients in the past with a diagnosis of dementia or with mental health needs, however it was very rare. Staff stated that these patients would be provided with more time for an appointment and could also be supported in their appointment by a family member. The service did not have a specific policy for managing patients with complex needs.
- Staff explained the referrer would inform them if translation services were required and they would organise this in advance. The service had an agreement with a translation phone service to provide access to an interpreter if needed. Staff stated that in most cases, patients were accompanied by a relative who could translate for them, however it was not clear if this was reflected in the policy or had been risk assessed.

Access and flow

- **People could access the service when they needed it.** Waiting times from referral to treatment to discharge of patients were in line with good practice.
- Staff told us patients were generally offered appointments the same week (depending on if patients preferred a specific time or consultant). However, the service did not have evidence to show this data was collected and monitored. Staff stated that they did not operate a waiting list as there had never been long delays for seeing patients.
- Patients told us they were given appointment times that suited them. The service planned to see patients at the time of their choice and had confirmation discussion with the patient.
- Staff booking one-stop patients informed them the whole appointment times were for two hours. This allowed time for patients to be seen by the consultant, have their diagnostic tests, and then also receive the results. Staff stated the appointments were normally shorter, however planned for two hours to ensure there was enough time for additional consultation or examination if needed.
- Consultants ran specific clinics every week. If the preferred consultant had no suitable slot available for the patient due to full bookings, the patient was given the consultant's private secretaries details to make an appointment with that same doctor at another one of their clinic sites. Where there was no named consultant on the referral, the patient was given a choice of dates and times to suit their preference.
- Patents were happy with reporting times. Diagnostic reports were usually available on the same day. Staff stated that they may require longer if there was a complicated case, however in this event they would ensure the patient was well informed.
- The service ran on time and staff informed patients when there were disruptions to the service. All patients said there was minimal waiting time when visiting the service.
- Staff confirmed that where patients missed their appointments they were contacted immediately and offered the next available appointment as needed. Staff stated they did not have many patients not attending appointments, but did not routinely collect or analyse this data.
- The service had no cancelled appointments between November 2017 and November 2018.

Learning from complaints and concerns

- **The service treated concerns and complaints seriously, investigated them and learned lessons from the results, and shared these with all staff.**

- Staff stated they would aim to resolve any patient complaints and concerns immediately. Staff were all aware of the complaints procedure and who had overall responsibility for managing the procedure.
- There was a complaint management policy in place. The complaints policy differentiated between formal and informal complaints, with defined timescales for the provider to acknowledge and respond to formal complaints. The complaints policy did not make reference to the service's duty of candour.
- Patients had access to complaint forms providing information about how to give feedback or raise concerns. Patients stated they were not aware of the complaints procedure or how to make a complaint, but were confident the service would aim to resolve any issues quickly.
- The service had received seven complaints received between November 2017 and November 2018. The service examined these complaints through the formal complaints procedure and they were resolved. Two of the seven complaints related to possible misdiagnosis. These complaints were investigated by the MAC and externally reviewed by colleagues at another service. We reviewed the complaints process and found both cases were well investigated.
- The MAC advisory committee reviewed the investigation of complaints and outcomes were shared with staff in team meetings.

Are outpatients and diagnostic imaging services well-led?

Good

We rated this service as good.

Leadership

- **Managers at all levels in the service had the right skills and abilities to run a service providing high-quality sustainable care.**
- The service had a clear management structure where the registered manager had responsibility for day to day running of the service, and clinical director was responsible for medical oversight. Staff knew the management arrangements and their specific roles and responsibilities.
- The registered manager was formally appraised annually by the managing director and "360 feedback" was provided by staff. The clinical director had oversight and appraisal of consultants through the Medical Advisory Committee (MAC).
- We observed members of staff interacting well with the leadership team during the inspection. Management of the service appeared to be approachable and there was a good culture amongst the team.
- Staff told us the registered manager and clinical director were very approachable and supportive, and they could reach them when needed. All the staff were positive about the management of the service, and felt the service was run efficiently.
- The service had a service level agreement with a nearby NHS trust to provide the role of Radiation Protection Adviser (RPA).

Vision and strategy

- **The service did not have a vision for what it wanted to achieve or workable plans to turn it into action.**
- The service did not have a specific vision or strategy document for the service. Objectives and goals for service development would be discussed locally in the MAC, and business development objectives would be part of the corporate provider's business strategy. The current corporate business strategy ran until 2023, however did not include any specific developmental aims for the Harley Street Breast Clinic.
- Staff stated they felt they would be asked for their opinions and contributions when changes were being considered for the service. Staff were not aware of any specific vision or strategy for growing the service.
- The provider outlined their aims and objectives in a statement of purpose, which was on the "Aims of our Clinic" section on the website. The provider aimed to provide a one stop clinic for all breast investigations with diagnostic results made available as efficiently as possible.
- The manager stated the service was interested in new technologies that deliver improved diagnosis of breast conditions. The service had a plan to move from digital mammography to tomosynthesis (three-dimensional imaging) when the current mammography screening machine was due for replacement.

Culture

- **Managers across the service promoted a positive culture.**
- Staff were positive and happy in their role and stated the service was a good place to work. Staff felt there was a good working relationship between the various disciplines and this helped to offer consistent care to patients.
- Most staff told us they felt supported, respected and valued by the management. Staff stated that they could approach the managers about concerns if they needed to, and that they felt comfortable reporting incidents to them.
- There was good communication in the service from managers. Staff stated they were kept informed by various means, such as through team meetings and emails.
- The service had a corporate level whistleblowing policy and staff confirmed they could raise concerns with management. The overall provider also had a provider-wide whistleblowing hotline for staff to use if they saw or heard something they were not confident addressing directly with their manager or the person involved.
- Staff told us there were good opportunities for learning and personal development in the organisation. Staff stated they were supported to pursue development opportunities which were relevant to the service, such as attending conferences, and they completed an annual appraisal as part of this.
- Staff were proud of the work they carried out. They enjoyed working at the service; they were enthusiastic about the care and services they provided for patients.

Governance

- **The service systematically improved service quality and safeguarded high standards of care by creating an environment for excellent clinical care to flourish.**
- There was a robust corporate and local governance framework in place which oversaw service delivery and quality of care. This included a quarterly MAC which was led by the corporate managing director, and attended by consultants, radiologists, and the registered manager.
- We saw records of the last four MAC meetings and saw they discussed audits, incidents, Key Performance Indicators (KPIs), training, compliance and any other clinical issues and audits. The meeting was minuted for dissemination to other staff who did not attend.
- The service had effective systems to monitor the quality and safety of the service. The use of audits, risk assessments and recording of information related to the service performance was to a high standard. The service completed regular clinical audits and monitored KPIs, and adapted service delivery in response to the results or outcomes.
- The service had good systems to identify risks, and plans to control or reduce risks as much as possible. Risks could be identified through being raised by staff, the regular MAC, frequent audits, or from patient feedback.
- The provider disseminated information to staff in team meetings or through email. These included minutes of meetings, updated or new policies, changes in legislation or best practice, and service developments.
- Staff were clear about the governance structure in the organisation and stated they were confident the systems in place supported the delivery of clinical care.

Management of risk, issues and performance

- **The service had good systems to identify risks, plan to eliminate or reduce them, and cope with both the expected and unexpected.**
- The service had a risk register which was part of the corporate providers risk management system. We reviewed this register and found consistent evidence of risks being identified and action plans put in place to control or eliminate the risk. Risks were given a date.
- The overall provider had a quality manual which outlined the quality management system for managers in all of the corporate provider's services. We reviewed this document and found that the management of risk and monitoring of quality was being delivered in line with this policy.
- The provider had systems to monitor performance, including incidents, patient feedback, audits and staff appraisals. These systems highlighted areas of good practice and opportunities for learning.
- There was a Unilabs business continuity policy, which included specific plans for the service. The plans included specific scenarios (such as electricity failure or

building restriction), and actions for staff to take in managing this disruption efficiently. The policy showed evidence that staff from the service were involved in developing the plans.

Information management

- **The service collected, analysed, managed and used information well to support all its activities, using secure electronic systems with security safeguards.** We observed good practice from staff in relation to information management.
- The service had a service level agreement with Unilabs IT services team to ensure computer systems were operational, and issues were addressed quickly. Staff told us there were sufficient numbers of computers in the service and IT support was satisfactory.
- All staff demonstrated they could locate and access relevant information and records easily, this enabled them to carry out their day to day roles.
- Relevant information for the running of the service, such as policies and team meeting minutes, were available in a shared drive which all staff could access. Staff were also required to sign and date when they had read the policies relating to information security.
- The service uploaded diagnostic images on a secured electronic portal for a second read of results remotely by another consultant. Images for patients were uploaded to an electronic portal, and results were retained in the electronic patient record. This could then be shared with other healthcare professionals and referrers.
- Senior staff informed us they were General Data Protection Regulation (GDPR) compliant and that patient information was managed in line with data protection guidelines and legislation. This was reflected in the services medical records retention policy and information security policy. Staff had received training on information governance as part of their mandatory training.

Engagement

- **The service engaged with patients and staff to plan the delivery of services.**
- The service had completed an annual patient satisfaction survey and used the feedback to inform the delivery of care and service development. For example, admin staff now ensure patients were aware at the time of booking that their appointment for a one stop clinic will take approximately two hours, so patients can ensure they were not rushing back to work or under undue time pressure.
- The service had an informative website that provided information to patients on the investigations provided, explanations of procedures, the fees, location, and details on how to make an appointment.
- There was good communication in the service from managers. Staff stated they were kept informed by various means, such as through team meetings and emails.

Learning, continuous improvement and innovation

- **The service was committed to improving services by learning from when things went well or wrong, promoting training, research and innovation.**
- All staff were supported to pursue development opportunities which were relevant to the service, such as attending specialty conferences and training.
- The service had also developed specific consent forms for stereotactic biopsy and mammograms for patients with breast implants, which provided information and expected outcomes on the procedures, as these examinations may involve additional discomfort.
- The service had a plan to move from digital mammography to tomosynthesis (three-dimensional imaging) when the current mammography screening machine was due for replacement.

Outstanding practice and areas for improvement

Outstanding practice

- The one stop breast clinic provided consultation and diagnosis for patients, with results generally available on the same day. Results were double read by two consultant breast radiologists. The results were sent to
- the patient and their elected GP or referrer.
- The service did not employ a breast care nurse as part of the service, however they did have a positive working relationship with a senior breast care nurse at the location where most patients would have treatment following diagnosis. Staff stated the breast care nurse was available to visit the service and could provide information to patients who may be receiving a difficult diagnosis.
- The service had also developed specific consent forms for stereotactic biopsy and mammograms for patients with breast implants, which provided information and expected outcomes on the procedures, as these examinations may involve additional discomfort.
- Senior staff informed us they operated a provider wide "Care Big" philosophy to ensure patients were treated with respect, were made to feel at ease, and that they had as much choice as possible in their care. All staff were aware of this approach to care, and the service manager was a provider wide ambassador for the philosophy.

Areas for improvement

Action the provider SHOULD take to improve

- The policy for using interpreting services should reflect that family members may offer translation, and that this has been risk assessed.
- Update the service incident policy and complaints policy to reflect compliance with duty of candour legislation.
- Consider collecting information around waiting times and cancellations to inform where service delivery could be improved.