Guidance on screening and symptomatic breast imaging

Fifth edition

Contents

Introduction

This document replaces the RCR's previous Guidance on Screening and Symptomatic Breast Imaging, Fourth edition, which is now withdrawn. This does not replace NHS BSP guidance which should be followed.[1] A review of the previous edition has been undertaken with relevant updates applied in light of new evidence and changing clinical trends. A new section on Artificial Intelligence has been added which is expected to expand considerably with future editions.

Within these guidelines, we have tried to use inclusive and descriptive language to describe the people to whom the guidelines refer. There are exceptions, such as:

- when the evidence for the recommendation has not been reviewed and we are not certain that it can apply to other groups of people
- when evidence has been reviewed, but the information is too limited to make specific recommendations
- too few recommendations have been updated to reflect new evidence or a change in practice

We therefore expect healthcare professionals to consider the needs and preferences of each individual patient, treating them with dignity and respect, while using their clinical judgement to implement recommendations most appropriate to their gender.

1. Investigation of breast symptoms

Diagnostic assessment of people with breast symptoms is based on 'triple assessment' (clinical assessment, imaging and, where appropriate, biopsy).[2] The tests used in each case are determined by the symptoms, clinical findings, and age of the person.

Breast imaging facilities should, as a minimum, include digital mammography and high frequency ultrasound with probes and machine settings appropriate for breast imaging. The technical quality of mammography should be equivalent to that in the National Health Service Breast Screening Programme (NHSBSP). Digital breast tomosynthesis (DBT) and contrast-enhanced mammography (CEM) may also be used in the symptomatic setting, where available.

Imaging assessment

- Imaging should be carried out by suitably trained members of the multidisciplinary team.
- Interpretation of breast imaging is best supported with all previous breast imaging, and systems should be in place to ensure its timely availability.
- Ultrasound is the first line imaging modality of choice in women aged <40 years and during pregnancy and lactation.
- Mammography is the first line imaging modality of choice in women aged 40 years or over, with the addition of ultrasound as indicated.
- Mammography should be performed on all people with confirmed malignancy, irrespective of age.
- Mammography should be considered on people aged <40 years with clinically suspicious findings (P4 or P5).

- Mammography should be performed on people with sonographically suspicious (U4 or U5) findings, preferably prior to biopsy.
- Mammography should include mediolateral oblique (MLO) and craniocaudal (CC) views of each breast.
- If a suspicious abnormality is identified on mammography it may be helpful to perform further mammographic views (magnification, compression or DBT) to help characterise the abnormality.
- DBT or CEM may be considered as a first line investigation instead of 2D mammography in people with clinically suspicious findings.[3,4]
- The level of suspicion for malignancy should be recorded for each breast using the British Society of Breast Radiology (BSBR) imaging classification U1–U5 and M1–M5 (Appendix 1). Mammographic and or/sonographic lesion sizes should be recorded in the imaging report.
- Ultrasound of the axilla should be carried out in all people when invasive malignancy is suspected or confirmed. The imaging report should document the number of abnormal nodes as well as scores for the abnormal nodes. If lymph nodes show abnormal morphology, biopsy of at least one of these nodes should be performed under ultrasound guidance. There is currently no agreed threshold for cortical thickness and this should be audited and determined locally. The BSBR AVOID (Audit to quantify the VOlume of disease on axillary ultrasound in the axilla, by assessing the cortical thickness and number of abnormal noDes, to support surgical management of the axilla) audit was opened in early 2024 and is now closed with publication planned for 2025. This aims to standardise approaches to evaluating the axilla.

Contrast Enhanced Mammography

- In recent years, Contrast Enhanced Mammography (CEM) has become more widely available. This technique, involving the administration of iodinated contrast agent to image the abnormal vasculature associated with tumours, improves the sensitivity of mammography and has similar indications to breast MRI.[5,6] The examination consists of the two standard mammographic views of each breast (cranio-caudal and medial lateral oblique projections), with two sets of images obtained - a low energy image and a recombined image. When interpreting CEM, reference should always be made to previous breast imaging.
- The low energy image is comparable to a normal digital mammogram and is reported in the same way; with reference made to standard mammographic features such as breast density, lesion morphology, size, multifocality and location. The recombined image shows areas of contrast agent enhancement and therefore provides additional information. Descriptors used when interpreting the recombined images are similar to those employed in breast MRI. For instance, it can be useful to comment on the presence or absence of background parenchymal enhancement. Lesions seen on the recombined image can be classified as showing mass or non-mass enhancement.
- The American College of Radiologists has produced a comprehensive extension to the BI-RADS lexicon for CEM, which is a useful reference guide for lesion descriptors and reporting terminology.[7] It is important to interpret both sets of images together rather than in isolation. Consequently, a lesion is reported and classified based on the information available from both the low energy and recombined images. The use of an overall risk scoring system for the CEM study is helpful, such as the 1-5 scale recommended for other breast imaging modalities (1- Normal, 2-Benign, 3-Indeterminate, 4-Suspicious and 5-Malignant).

Needle biopsy

- Clinical and imaging work-up should ideally be completed before needle biopsy is performed.
- Breast biopsies should be performed under appropriate image guidance whenever possible.
- Axillary biopsies should be performed under ultrasound guidance.
- For needle sampling of both breast lesions and axillary nodes, core biopsy should be performed rather than fine-needle aspiration cytology (FNAC) as it provides higher sensitivity and specificity and provides important prognostic oncological information (tumour type, grade and receptor status).[8]
- Freehand (clinical) core biopsy is indicated in cases where imaging is normal but there is an indeterminate or suspicious clinical abnormality (P3 or above, confirmed on senior surgical review if necessary).
- Biopsy of lesions within or attached to skin may be carried out using a punch biopsy needle under local anaesthetic (usually by a member of the surgical team). This is particularly suitable for suspected Paget's disease of the nipple and local recurrence within the skin.
- Lesions which are not possible to biopsy should be discussed in a MDT setting to consider management options.
- The management and follow-up of B3 lesions in the symptomatic setting should follow NHSBSP Assessment guidance for B3 lesions (screening setting) in the absence of further evidence. Please see section 4.

SPECIFIC SYMPTOMS:

Lump/Change in texture

- In women aged 40 years and over, mammography and targeted ultrasound should be performed.
- In women under 40 years ultrasound should be performed as the first line imaging modality.
- Mammography should be performed in women under 40 years for lesions which are sonographically suspicious (U4 or U5).
- Mammography may be considered in women under 40 years with suspicious clinical findings (P4 or P5).
- Most solid breast lesions will require a needle biopsy to complete the triple assessment and establish a diagnosis. Patients with U3, U4 or U5 findings should undergo biopsy.
- In the following cases, clinical and imaging information alone may lead to the diagnosis and biopsy may not be required.
    - Presumed fibroadenoma – In patients under 30 years of age, a biopsy is not indicated if the following criteria are satisfied – ellipsoid shape, wider than tall, well-defined outline with fewer than four gentle lobulations, no calcification or shadowing and a thin echogenic pseudocapsule.[9,10,11,12]
    - Presumed fat necrosis – If P2, imaging is typical and there is a clear history of a cause (for example local trauma, surgery, fat graft) then biopsy is not required.
    - Presumed lipoma or hamartoma – If P2 and imaging is typical no biopsy is required. Morphologically normal intramammary lymph node.

- If there is any doubt about the nature of the lesion, or if there is a discrepancy between imaging and clinical features, biopsy should be performed.
- Multiple lesions should be carefully assessed to establish whether they have the same morphological features and are likely to be due to the same pathology. Where there are multiple masses in the same breast, thought most likely to be fibroadenomas, biopsy of one lesion (usually the largest or radiologically least typical) is sufficient for diagnosis. In the case of multiple suspicious lesions, biopsy of more than one lesion is usually required to establish disease extent and guide appropriate treatment. In such cases, the lesions furthest apart should be biopsied.
- Breast cysts are a very common cause for breast lumps. Anechoic simple cysts do not mandate aspiration, however ultrasound guided aspiration may be offered for symptomatic cysts. Cysts with a solid component, or which have residual soft tissue seen post-aspiration, should be subjected to biopsy. If blood is aspirated from a cyst, unless there is a clear history of a traumatic procedure, the aspirate should be sent for cytological assessment. In cases of multiple cysts it is not usually necessary to document the size and number of cysts.

Nipple symptoms

- Mammography is indicated in women aged 40 and over.
- Targeted ultrasound should be performed if there is a palpable abnormality and for investigation of a single duct clear or blood-stained discharge.

Breast pain

- Breast pain is a very common symptom in the adult population and sufferers frequently present to primary care with many referred onwards for secondary care evaluation.
- Breast pain alone is not a sign of breast cancer, and in isolation is not an indication for imaging.[13,14,15]
- Based on current available evidence, it is therefore recommended that patients presenting with breast pain only (generalised or focal) are not routinely offered imaging to investigate these symptoms. However, if there is separate clinical concern regarding a pathological aetiology, patients should have access to imaging in a timely fashion (<2 weeks).
- The BSBR offers this guidance in full support of efforts by the Association of Breast Surgery (ABS) to develop and assess new appropriate breast pain only pathways nationally and we await the results of their assessment of the various pathways.

Axillary lump (without clinical breast abnormality)

- Targeted axillary ultrasound is usually sufficient as a first-line imaging investigation.
- Benign axillary findings on ultrasound (for example fat pad, accessory glandular tissue, sebaceous/epidermal cyst) negate the need for further imaging of asymptomatic breast tissue.
- Mammography should be performed in people with suspicious findings on axillary ultrasound.
- If there is suspicious axillary lymphadenopathy without another explanation (for example rheumatoid arthritis or chronic lymphocytic leukaemia) then whole breast ultrasound (WBUS) is recommended unless the breast is entirely fatty on mammography. If core biopsy demonstrates metastatic carcinoma suggestive of origin from a breast primary and mammography and WBUS are normal, further imaging (MRI breast or CEM) is indicated. If a

non-breast primary is suspected, contrast-enhanced computed tomography (CT) of the chest, abdomen and pelvis is indicated to look for primary malignancy elsewhere. PET-CT may be considered.

Breast implants

Imaging is dependent upon whether the clinical findings are suggestive of breast cancer or are felt to be related to a complication of the breast augmentation.

Symptoms and signs suggestive of breast cancer should be investigated with triple assessment as above. The patient should be counselled about the small risk of damage to implants from mammographic compression and the reduced sensitivity of mammography.[16] Patients should also be warned about the small risk of implant damage from percutaneous biopsy.

Clinical findings of implant related complications may have ultrasound alone as first-line imaging investigation.

Most benign complications of breast augmentation can be diagnosed with routine imaging. Examples include silicone granulomas and silicone infiltration of axillary lymph nodes, which have characteristic sonographic appearances. It is important to note that the latter does not indicate the presence of implant rupture when found in isolation and therefore should not prompt further investigation of asymptomatic breasts.

A normal ultrasound has a high negative predictive value for implant rupture, and further investigation to establish implant integrity is not usually required. Similarly, unequivocal signs of rupture on ultrasound do not mandate further imaging. If the ultrasound findings are equivocal then dedicated non-enhanced breast implant protocol MRI is recommended. The implant type and any history of prior implants and implant rupture should be included on the request. There is no evidence of a health risk when free silicone is left in situ, and therefore aggressive investigation of breast implants and their benign complications is not indicated.[17]

Breast specialists must be aware of the possibility of breast implant associated-anaplastic large cell lymphoma (BIA-ALCL), a rare complication of implant breast augmentation. People who present with a late onset (>one year) persistent peri-implant seroma (particularly if the implant is of the textured type) should be investigated urgently with ultrasound in the first instance. Aspirates and capsule tissue samples should be collected and sent for urgent dedicated cytological and histopathological analysis. The differential diagnosis of BIA-ALCL should be included on the pathology request.

Male breast imaging

Mammography and/or ultrasound should be performed in men with unexplained or suspicious unilateral breast enlargement. If the clinical features are typical of gynaecomastia (P2) then imaging is not required.[18]

Unless clinically suspicious (P4 or P5) it is not usually necessary to perform both mammography and ultrasound.

Ultrasound is recommended for men below the age of 40. For men aged 40 and over, ultrasound or bilateral mammography may be used. The ‘rolled-nipple’ technique may be useful for demonstrating subareolar ducts and confirming the typical appearance of subareolar gynaecomastia.[9]

Biopsy should be performed following imaging in those with uncertain or suspicious radiological findings (M3-5 or U3–5) or where indeterminate clinical findings (P3) are not adequately explained by benign imaging findings.

2. Population screening

Guidance for radiologists and mammography readers on breast cancer screening of asymptomatic women has been previously published by the NHSBSP.[19]

General principles

The client should be provided with information detailing the risks and benefits of screening mammography before the examination.

The technical quality of all screening mammography and the training of those performing the examinations should be at least to the standards required by the NHSBSP.[20]

Screening mammography should be interpreted by readers who satisfy the professional standards required by the NHSBSP.[21]

Two-view digital mammography (MLO and CC projections of each breast) is required at each attendance.

Tomosynthesis, which produces three-dimensional images using a low-dose x-ray system, has been approved for use in the NHSBSP as an optional extra tool in the breast screening assessment clinics. It is not currently used for routine screening outside of a clinical trial.[22]

In breasts with implants, supplemental images using the modified compression displacement technique should be employed where possible.[23]

Double reading of screening mammograms is mandatory.[21]

There is insufficient evidence to support the use of ultrasound as a screening tool.

Mammographic density is currently not recorded in the routine NHSBSP. Research is being conducted to assess appropriate imaging techniques across the range of risk factors.[24]

Screening, wherever performed, should always include formally agreed mechanisms for referral, without delay, of people with screen-detected abnormalities to a specialist breast team.

Mammographic screening of women aged 50 up to 71st birthday

There is strong evidence from randomised controlled trials that population screening of women between the ages of 50 and 70 years by mammography alone can reduce mortality from breast cancer. The NHSBSP provides screening by invitation every three years for women aged 50 up to 71st birthday in the UK.

Screening women after 71st birthday

There is no evidence from randomised controlled trials to support routine population screening of women over the age of 71, who are more at risk of screening overdiagnosis than younger women. The results of the UK age extension trial screening women aged 71–73 (and 47–49) taking place in England and Wales are not expected for several years.[25] With recent increases in life expectancy

there may be some older, otherwise fit women who may benefit from screening, and women can self-refer for three-yearly mammography in the NHSBSP.

3. Risk-adapted screening

Currently many women who are known to be at moderate or greater risk of breast cancer are offered additional screening. A subset of these women will have the highest risk category, known as 'very high-risk' (VHR). The NHSBSP for VHR women has been established since 2013. The VHR screening programme provides annual MRI and mammographic screening. Details for the protocols that should be followed for each specific risk group can be found on the NHS BSP website.

The VHR population can be distinguished from the 'high-risk' group defined by the National Institute for Health and Care Excellence [NICE]. Women in high- and moderate-risk groups as defined by NICE may be offered screening outside the NHS BSP.

To differentiate between the NICE and NHS BSP guidance, very high risk is defined by the NHS BSP as:

- women with a lifetime risk of 40% or greater due to a specific genetic abnormality in the woman or her family
- those who received radiotherapy to breast tissue during treatment for Hodgkin and non-Hodgkin lymphoma between the ages of 10 and 35 years
- a small number of women who received radiotherapy to breast tissue during treatment for cancers other than lymphoma

Referrals into the NHS BSP Very High Risk (VHR) screening program have been streamlined, and include women who have had radiotherapy to sites involving the breast for cancers other than lymphoma. These women should be placed onto the BARD (Breast screening After Radiotherapy Dataset) registry for risk assessment.[26]

Since the previous edition of these guidelines there has been a revision to the published NHS BSP guidance. The revisions are focused on:

- clarifications on the cohort of women entitled to VHR screening following supradiaphragmatic radiotherapy
- breast density review process
- screening during pregnancy and lactation
- screening transgender and non-binary people

Some of the risk calculators, such as Tyrer-Cuzick version 8, incorporate breast density in addition to personal factors and family history. It is therefore recommended that breast density is stated on the surveillance mammography report for very high risk people using an appropriate and available method (automated or visual analogue scales) using the BI-RADS Atlas Reporting System. No optimal method of breast density measurement has been identified but should be consistent through an individual breast unit population. Women with BI-RADS B-D should be offered MRI screening, with only women with an entirely fatty breast (BIRADS A) being unlikely to have additional value from annual MRI in addition to mammography. Breast density checks should be performed annually (if BIRADS B,C or D) until screening stops.

Screening women in pregnancy and lactation is safe, but as the breast density increases during pregnancy, the effectiveness of mammography reduces. Women can be screened during lactation but are advised to breastfeed or express milk prior to examination. Shielding is not considered necessary due to the low radiation dose of mammography.

MRI during pregnancy is not recommended due to the high level of background parenchymal enhancement during pregnancy and lactation that significantly reduces the sensitivity of the examination.

Recommendations for the surveillance of women with both a personal and family history of breast cancer are included in the most recent NICE clinical guideline 164 updated November 2023.[27]

CG164 outlines the most appropriate screening modality and frequency for women at moderate and high risk of breast cancer. MRI is not routinely recommended for women in this risk category, but can be considered.

For those unable to tolerate MRI, or where it is contraindicated, non-contrast MRI should not be performed. Breast ultrasound is not routinely provided by the NHS BSP as a screening tool but may be considered if a screening MRI cannot be performed. The women should be made aware of the reduced sensitivity and specificity of US compared with MRI screening.

Screening MRI (whether performed inside or outside the NHSBSP) should be performed and reported to NHSBSP standards, including the double reading of the examination.[28] Reporting of Breast MRI must include all anatomy on the images (to allow for incidental findings). Reporting limited to breast tissue only is not recommended.

Standard sequences that should be included in the screening breast MRI protocol should be performed as per NHSBSP guidance (appendix 2).[28]

Abbreviated and FAST MRI protocols are currently being evaluated to ensure the sensitivity and specificity of breast MRI is not compromised with these more time efficient protocols. Currently they are outside of the standard recommendations for screening very high risk populations.

An important revision to NHS BSP breast screening guidance outlines recommendations for the screening of transgender (trans) and non-binary people.

Transgender men who have not had chest reconstruction (top surgery) or if there is still residual breast tissue following chest surgery should be offered regular screening. If they are registered with their GP as male, they will not be automatically invited for breast screening. Discussion with the GP to support referral for screening at the local breast unit is recommended.

Trans women who are registered with their GP as female will be routinely invited to screening. Routine screening is recommended for those who are taking long-term hormonal therapy as they may be at increased risk of developing breast cancer, and once again further patient- GP discussion is advised.

4. Screening assessment

All people recalled following an abnormal screening mammogram, screening breast MRI or recalled due to symptoms mentioned at the time of screening mammogram will undergo triple assessment at second stage screening in accordance with the NHS BSP Clinical Guidance for Breast Cancer Screening Assessment.[29]

The Responsible Assessor is responsible for the overall assessment, although several disciplines may be involved in different aspects of the assessment.

Triple assessment consists of further imaging (further mammography and/or ultrasound), clinical examination and tissue sampling if appropriate.

Digital breast tomosynthesis (DBT) may be used for screening assessment and only the affected breast should be imaged. Two-view DBT should be performed and often the need for additional 2D views is not required. In the case of calcifications, a combo (2D+3D) lateral view may be performed but traditional supplementary views – lateral and magnification views are still required.[30]

Breast ultrasound should be performed in most cases, and in all cases where a soft tissue abnormality was suspected on the initial screening mammogram.

CEM is expected to be approved for use in screening assessment as the current screening assessment guidelines are being updated and are due publication in 2025.

Abbreviated breast MRI is not currently approved for routine use in second stage screening assessment and should only be used in the context of research.

Tissue sampling may be performed under stereotactic, DBT, ultrasound or MRI guidance. Needle core biopsy (either conventional 14-gauge or vacuum-assisted biopsy) is recommended for breast lesions. Marker clip placement is advised following all stereotactic procedures. A marker clip should be considered in ultrasound-guided biopsies to confirm the correct area has been sampled. For example:

- where the target lesion may be difficult to perceive
- where there is any doubt that the lesion seen on ultrasound corresponds to the mammographic abnormality
- where multiple lesions in the same breast have been biopsied.

Core needle biopsy is recommended for axillary lymph nodes rather than FNA.[31] All cases where tissue sampling has taken place will be discussed at a multidisciplinary meeting (MDTM). In cases where tissue sampling has not taken place, the case will be reviewed by another Responsible Assessor to confirm agreement with the assessment outcome, and this should be documented prior to final discharge.

5. Staging of breast cancer

Staging of the Breast

Initial evaluation of the breast is undertaken with mammography/DBT/CEM and ultrasound. A minimum of whole quadrant ultrasound of the index lesion should be performed to assess for multifocal disease.

DBT may have incremental cancer detection rates over full-field digital mammography (FFDM) for multifocal disease, and may have superiority over FFDM for pre-operative size measurement, with equivalent accuracy to FFDM combined with compression mammographic views at imaging assessment.[32-35]

Breast MRI is indicated for local staging of breast cancer in the following cases: [28-30]

1. If breast conservation is being considered and there is discordance of size on clinical examination and conventional imaging (mammography/DBT and ultrasound)

2. If breast-conserving surgery is being considered for invasive cancer with a lobular component (invasive lobular carcinoma or mixed carcinomas with a lobular component)* [36,37]

3. In mammographically occult tumours

4. Where there is suspicion of multifocal disease, but unconfirmed on conventional imaging or if assessment is challenging due to breast density

5. In the presence of malignant axillary node(s) with no primary tumour evident in the breast on conventional imaging

6. In Paget's disease of the nipple if breast conservation is being considered.[38]

*The indication for MRI in invasive lobular cancers (or mixed carcinomas with a lobular component) is to assess disease extent in the ipsilateral breast, and not to screen the contralateral breast. Therefore MRI is not recommended in cases of invasive lobular carcinoma where mastectomy for the known cancer is planned (or has been performed).[33,34]

CEM has comparable accuracy to dynamic contrast-enhanced MRI for T-staging and assessing for multiple primary tumour foci.[35,39-41]

If gadolinium administration is contraindicated, consider CEM or diffusion-weighted imaging (DWI).[42]

Staging of the Axilla

Axillary ultrasound is indicated to assess nodal disease burden at time of diagnosis. Documentation of the number of abnormal axillary lymph nodes is recommended.

Core biopsy of abnormal axillary lymph nodes is more sensitive than FNAC.[31]

Staging for distant metastatic disease

Metastatic disease at presentation occurs in only 4% of newly diagnosed breast cancer patients and therefore whole-body staging is not required in the vast majority of cases.[43]

Indications for whole-body staging in breast cancer include:

1. T3 and T4 primary breast cancers

2. ≥4 abnormal axillary lymph nodes at axillary ultrasound or ≥4 macrometastatic axillary lymph nodes at axillary surgery

3. If patient symptoms raise the suspicion of metastatic disease

At present, there is no evidence base for carrying out staging prior to neoadjuvant chemotherapy in ≤T2 tumours with ≤N1 disease.[44]

Contrast-enhanced CT of the thorax, abdomen and pelvis (CT TAP), incorporating the supraclavicular fossae and proximal femora, is the modality of choice in most cases. CT TAP is more accurate than staging with chest x-ray, liver ultrasound and Tc99m-methylene diphosphonate (MDP) bone scintigraphy. Bone scintigraphy is not routinely indicated in addition to CT TAP in the absence of bone symptoms.[45-48]

Following equivocal results of CT, other targeted imaging modalities may be indicated, such as MRI liver.[43]

Fluorodeoxyglucose (FDG) positron emission tomography–computed tomography (PET- CT) can detect additional locoregional and distant metastases in approximately 10% of patients with inflammatory breast cancer and is advised for this indication.[49] PET-CT should be performed instead of and not in addition to CT TAP in cases of inflammatory breast cancer.[50]

FDG PET-CT is also indicated in problem-solving when other imaging modalities are indeterminate.[51]

Whole-body MRI (WB-MRI) may be utilised for baseline staging and is valuable in further evaluating cases which are equivocal on other imaging modalities.[52]

WB-MRI is the imaging technique of choice in pregnant women with breast cancer, who meet the criteria listed above for staging for metastatic disease.[53]

If symptoms raise suspicion of intracranial metastases, a contrast enhanced CT of the brain is recommended, with MRI of the brain reserved for problem solving.

Follow-up of metastatic disease

For monitoring metastatic disease where appropriate, CT TAP (incorporating the supraclavicular fossae and proximal femora) is usually sufficient. As above, FDG PET-CT or targeted MRI, can be used for problem-solving following equivocal results of CT.

For follow-up of skeletal disease, CT is usually sufficient.

In oligometastatic disease, FDG PET-CT should be undertaken to refute the presence of other metastatic disease if radical treatment is being considered for a presumed single site of relapse.[43]

Imaging assessment of response may not be required in all instances, particularly in cases of local therapy for specific palliation.

6. Monitoring of response to neoadjuvant drug treatment

Locoregional staging should include digital mammography, breast ultrasound and dynamic contrast enhanced Breast MRI at baseline. End of treatment imaging should be performed to aid surgical planning. MRI is the most accurate imaging technique and correlates best with pathological findings post-treatment. [54-57] Mid-treatment scanning with MRI may be considered of importance in response-adapted therapy and may be performed if appropriate to guide management. Diffusion-weighted imaging (DWI) has the potential to be of use if protocols are standardised.[56]

CEM has a growing evidence base in response assessment that suggests that it is likely to have a similar accuracy to MRI.[58] Monitoring of treatment response with CEM may be appropriate if this has also been obtained at baseline staging.

Where MRI or CEM is performed at the end of NAC, mammography and ultrasound at the end of treatment are unnecessary.

PET-CT is not presently recommended to monitor treatment response.[59]

Insertion of a marker clip is recommended prior to treatment. This is recommended even for those women in whom the decision to perform mastectomy has already been taken. Marker clips aid the pathologist in assessment of the tumour bed for complete pathological response which has prognostic implications.[60]

Marker clip insertion into a biopsied axillary node may be indicated so that limited axillary surgery can be offered in case of complete radiological response on end of treatment MRI. Radiographic confirmation of removal of the nodal marker clip in the specimen x-ray is recommended at the time of surgery.

Routine mammography to look for residual microcalcification following NACT is not necessary.[61]

7.

Imaging follow-up after breast cancer treatment

People treated for breast cancer are at risk of developing local recurrence or a second breast primary, with associated increased rates of distant metastasis and breast cancer mortality. Surveillance after primary breast cancer aims to detect recurrent or new malignancy before symptoms develop to improve survival and quality of life. Clarity in the evidence base for standardised approaches to surveillance during and after breast cancer treatment remains elusive. Thus, determining the optimum frequency and duration of mammographic surveillance in different groups continues to be challenging in practice; this is especially true when proposing the most suitable surveillance regimens according to age, cancer biology and treatment provided. However, our improving recognition of the value of tailoring well-informed strategies to each individual patient along with access to rapidly evolving tools specifically designed to support practice are driving advances in this area. The recently published Mammo-50 trial can now contribute to this growing momentum and will continue to do so as its findings, recommendations and predictable subsequent works are disseminated and applied to empower better post-therapy management decision making by multidisciplinary teams.[62]

The pre-Mammo-50 status quo for imaging surveillance in the UK has typically been based on the established guidelines issued by the National Institute for Health and Care Excellence (NICE). At the time of writing this guide, NICE states: [41]

- Offer annual mammography for 5 years to all people who have had or are being treated for breast cancer, including DCIS. For women, continue annual mammography past 5 years until they enter the NHS Breast Screening Programme (NHSBSP) in England or the Breast Test Wales Screening Programme (BTWSP) in Wales.

It is important to note these provisions do not replace those for breast screening; eligible women diagnosed with breast cancer should still be invited for breast screening without interruption. [63] These

guidelines are now challenged by the Mammo-50 trial findings that are summarised and recommended for clinical use later in this section.

The rationale for mammographic surveillance after breast cancer surgery

The sensitivity for surveillance mammography in the detection of ipsilateral breast tumour recurrence (IBTR – this includes true local recurrences and second cancers in the ipsilateral breast) in women who have undergone breast-conserving surgery is 64–67%.[64] Women with mammographically-detected IBTR have better survival rates than those with IBTR first detected on clinical examination. [64]

Women who have had breast cancer have an increased risk of a primary metachronous contralateral breast cancer (MCBC) for at least 20 years compared to the general population. Patients with MCBC detected by routine mammography have better survival rates than patients with MCBC detected by other means. [65]

Young age is the strongest predictor of local recurrence, which is when screening lead time is shortest. Natural history demonstrates a decrease in the influence of early detection of breast cancer on key outcome descriptors as age increases. This suggests the risk of overdiagnosis is likely to increase with age. Imaging surveillance is an active intervention that leads to false positive diagnoses and over-diagnosis and treatment. As with all investigations, the benefits of imaging surveillance have to be balanced against their risks. Patients with significant co-morbidities may not be well-served by the general strategies recommended more broadly and this should be discussed with any suitable alternative arrangements being agreed fully prior to referral.

Mammographic surveillance recommendations drawn from the Mammo-50 trial findings

The findings from the Mammo-50 trial have been used to inform new guidelines for the post-operative mammographic surveillance of breast cancer patients reflecting a profession-wide keenness and sense of responsibility to achieve safe de-escalation whenever existing approaches have been shown to offer little or no net benefit. The default position for these guidelines continues to be the existing NICE guidance outlined above; that guidance should still be followed in women under 50 years of age and for all ipsilateral breast surveillance for the first three years post-surgery in line with the Mammo-50 trial design. The recommendation for annual contralateral mammographic surveillance following mastectomy has been dropped in favour of evidence-based age-adjusted screening intervals.

Mammography Surveillance Regime >50 years

	Invasive non-TNBC	DCIS or TNBC
Post-breast conserving surgery	Bilateral mammography in years 1, 2, 3 and 5 post-surgery	Bilateral mammography every year for 5 years post-surgery

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	Patients aged 50-60 years	Patients aged >60 years
Post-mastectomy	Biennial contralateral mammography	Refer to NHSBSP only*

WLE: Wide local excision
TNBC: Triple negative breast cancer
DCIS: Ductal carcinoma in-situ
NHSBSP: National Health Service Breast Screening Programme
*Automatic invitations cease in line with current NHSBSP specification

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552 **Ipsilateral imaging surveillance after mastectomy and reconstruction**

553 Routine imaging of asymptomatic mastectomy flaps with mammography and/ or ultrasound is not
554 recommended. There is insufficient evidence to recommend routine mammographic surveillance of
555 women following autologous breast reconstruction. [67]

556

557 **Surveillance using other imaging modalities**

558 Attempts to build an evidence case for using DBT in post-treatment surveillance have yet to bear fruit.
559 Early evidence suggests that MRI is the most accurate test for detecting ipsilateral and contralateral
560 breast cancer in previously treated primary cancer, but further studies to determine its clinical utility
561 and cost-effectiveness are needed. [65] Its use may be considered in young women, women with dense
562 breasts and women with mammographically occult breast cancers. This reflects current screening
563 recommendations for women at increased breast cancer risk nationally.[26]

564 Routinely supplementing mammography with whole-breast ultrasound increases referrals for further
565 investigations without conferring any survival benefits. [68] This practice is therefore not recommended
566 for routine surveillance following primary breast cancer.

567

568 **Imaging surveillance of the ipsilateral axilla**

569 Routine ultrasound surveillance of the asymptomatic ipsilateral axilla following breast cancer
570 treatment is not recommended.

Imaging surveillance in women in higher risk groups

Women already in higher risk groups who qualify for more frequent mammographic and/ or MRI screening should continue the same risk-adapted protocol after treatment for breast cancer without modification.[27]

Imaging surveillance in pregnancy and lactation

These surveillance guidelines apply similarly to patients who are pregnant or lactating.

Imaging surveillance in male breast cancer

Although the rates of male breast cancer are low, the risk of a second breast cancer is significantly higher than in the general male population. [69] In the absence of strong evidence describing the value of imaging surveillance specifically relating to males, the current guidance from NICE should be followed.

Symptomatic presentation after breast cancer treatment

Patients must be counselled to seek medical advice quickly should new symptoms potentially related to breast cancer recurrence develop. In turn, services must offer affected patients rapid access to triple assessment including mammography, ultrasound and biopsy and appropriate multidisciplinary team case review and discussion.

8. Artificial Intelligence

In the past few years there has been increasing interest in the utilisation of AI in the field of breast imaging. This is due to the promise of enhanced efficiency, accuracy, and consistency in breast cancer detection and diagnosis.

AI can play a multifaceted role in breast imaging, encompassing its applications in image interpretation, risk assessment, workflow optimization, breast density and personalized treatment planning. It is acknowledged that AI in some form is already being used in the breast services eg the smart clinic algorithm in the NBSS and in basic tools on RIS and PACS.

Currently, following a review of existing evidence in 2021[70], diagnostic AI is not recommended for use in the screening service unless as part of a trial or evaluation process. Continuing prospective evidence is being gathered in the UK and internationally to ascertain whether 2D or 3D AI is suitable for integration into the screening programme.[71-73] International data and research results are promising regarding AI in breast screening.

The purchase or use of AI in the symptomatic services should follow local Trust policy and advice.

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Appendix 1. Classification of imaging findings

Breast

These have previously been published as the Royal College of Radiologists Breast Group breast imaging classification.[74] A standardised classification aids communication of the perceived likelihood of malignancy and the need for further investigation.

The level of suspicion for malignancy on imaging should be categorised from 1 to 5, with each breast scored separately according to its most suspicious lesion. The numerical score should be prefixed to indicate the imaging modality – M (mammography), U (ultrasound).

1 Normal/no significant abnormality
   - There is no significant imaging abnormality.

2 Benign findings
   - The imaging findings are benign.

3 Indeterminate/probably benign findings
   - There is a small likelihood of malignancy. Further investigation is indicated.

4 Findings suspicious of malignancy
   - There is a moderate likelihood of malignancy. Further investigation is indicated.

5 Findings highly suspicious of malignancy
   - There is a high likelihood of malignancy. Further investigation is indicated.

MRI screening reporting categories[28]

MRI 1 Normal

- No enhancing lesions

MRI 2 Benign

- All non-enhancing lesions that are morphologically benign and have a benign enhancement curve

MRI 3 Indeterminate

- Probably benign, including morphologically unclear lesions with benign enhancement curve and also morphologically benign lesions with suspicious enhancement curve

MRI 4 Suspicious

- Suspicious morphology and enhancement curve

MRI 5 Malignant

- Malignant morphology and enhancement curve

Axilla

Variations of the above system have been applied to axillary ultrasound staging of the axilla. The following classification is recommended:

A1 Normal/no significant abnormality

- There is no significant imaging abnormality.

A2 Benign findings

- The imaging findings are benign.

A3 Indeterminate/probably benign findings

- There is a small risk of nodal metastatic disease. Biopsy is normally indicated.*

A4 Findings suspicious of malignancy

- There is a moderate risk of nodal metastatic disease. Biopsy is normally indicated.

A5 Findings highly suspicious of malignancy

- There is a high risk of nodal metastatic disease. Biopsy is normally indicated.

*Where there is a relatively low suspicion of malignancy (M3 and/or U3), biopsy of A3 nodes may only be necessary if breast malignancy is confirmed.

Appendix 2. Breast MRI equipment protocol and reporting guidelines[28]

Equipment

The minimum field strength should be equivalent to 1.5T, using a dedicated minimum 8-channel diagnostic breast coil.

Protocol (please see reference 26 for more detail)

The following sequences are mandatory:

- T2-weighted (T2W) fast/turbo spin echo sequence
- Dynamic contrast-enhanced (DCE) 3D T1-weighted (T1W) sequence

The following sequences are optional:

- Diffusion weighted sequence
- T1W non fat suppressed sequence
- High spatial resolution post-contrast T1W with isotropic voxels

Reporting guidelines

The use of consistent unified terminology using BI-RADS lexicon is suggested, although the final score should normally be using the UK system (Appendix 1).[75] The report should comment on breast composition and level of background parenchymal enhancement.

Reporting of Breast MRI must include all anatomy on the images (to allow for incidental findings). Reporting limited to breast tissue only is not recommended.

Appendix 3. Radiation risks in mammography

In 2017 Public Health England published a review, Radiation risk with digital mammography in breast screening which is based on a detailed study by Warren, Dance and Young.[76,77]

Risks from low dose radiation exposure from mammography are estimated from risks arising from acute high exposures, but the risk may be reduced at low doses and so a correction factor is often used. The average mean glandular dose is now 3mGy per two-view examination.[78] Warren et al presented results in which reduction factors of 1 and 2 were applied in the estimation to cover the range of published values, leading to a range of values in their results.[77] The main findings, assuming 20% mortality reduction, were that:

- The risk of a radiation-induced cancer for a woman attending two-view full field digital mammographic screening in the NHSBSP is between 1 in 49,000 and 1 in 98,000 per visit.
- If a woman attends all seven screening examinations between the ages of 50 and 70, the risk of a radiation-induced cancer is between 1 in 7000 and 1 in 14,000.
- The estimated number of cancers detected by the NHSBSP for every cancer induced is between 400 and 800.
- The mortality benefit of screening exceeds the radiation-induced detriment by between 150:1 and 300:1 (average of all ages), and this ratio increases with age.
- For the small proportion of women with breasts of compressed thickness greater than 90 mm, who receive higher radiation doses, the benefit exceeds the risk by between 100:1 and 200:1.[77]

The risks associated with breast screening for younger women and women at higher risk due to genetic factors were considered by Law, Faulkner and Young.[79] They found that benefits exceeded risk down to age 40 years. Faulkner found that although radiation risk was higher for BRCA1 and BRCA2 carriers, the risk/benefit ratio remained constant.[80] These considerations have been largely superseded by NHSBSP guidance on the screening of women at higher risk of developing breast cancer, which in most cases recommends MRI instead of, or in addition to, digital mammography.[26]

Appendix 4. Professional standards

Radiologists with a special interest in symptomatic breast imaging should:

- Meet at least level 1 competence in breast imaging (RCR training curriculum 2016) - preferably level 2
- Be part of a multidisciplinary team within a designated specialist breast unit
- Have appropriately contracted breast sessions - ideally 2, however preferably 3, programmed activities which should include participation in a diagnostic clinic
- Report a minimum of 500 symptomatic mammograms per year
- Participate regularly in breast MDTs
- Be proficient in mammography reporting, breast and axillary ultrasound, image guided breast and axillary needle biopsy, clinical history and examination as appropriate, issuing reports using recognised and recommended terminology, providing opinions as to likely diagnosis and recommendations for further procedures
- Participate in personal breast imaging audit and multidisciplinary breast service audit
- Comply with RCR training and CPD requirements.[81]

Terminology

AI	Artificial Intelligence
BIA-ALCL	Breast implant-associated anaplastic large cell lymphoma
BIRADS	Breast Imaging Reporting & Data System
BSBR	British Society of Breast Radiology
CC	Craniocaudal
CEM	Contrast-enhanced mammography
CPD	Continuing professional development
CT	Computed Tomography
DBT	Digital Breast Tomosynthesis
DWI	Diffusion-weighted Imaging
FDG	Fluorodeoxyglucose
FFDM	Full-Field Digital Mammography
FNAC	Fine-needle Aspiration Cytology
IBTR	Ipsilateral Breast Tumour Recurrence
MCBC	Metachronous Contralateral Breast Cancer
MDP	Methylene Diphosphonate
MLO	Mediolateral Oblique
MRI	Magnetic Resonance Imaging
NHSBSP	National Health Service Breast Screening Programme
NICE	National Institute for Health and Care Excellence
PACS	Patient Archive Communication System
PET-CT	Positron Emission Tomography - Computed Tomography
US	Ultrasound
WBUS	Whole Breast Ultrasound
WBMRI	Whole Body MRI

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