



Guidance on screening and symptomatic breast imaging

Fourth edition

November 2019

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Foreword

This fourth edition of *Guidance on Screening and Symptomatic Breast Imaging* is an update on the previous three editions, published in 1999, 2003 and 2013. It reflects the significant advances in technology and the role of imaging, image-guided diagnosis and intervention in the six years since the previous publication. The ongoing changes in the NHS Breast Screening Programme, risk-adapted and higher risk screening, indications for MRI and CT staging as well as post-cancer surveillance rationale are highlighted. The radiation risks associated with mammography are included in an appendix and can be used to provide the patient information required under IR(ME)R 2017.

I am extremely grateful to Dr Anthony Maxwell and members of the British Society of Breast Radiology for their help in revising and updating this guidance.

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Introduction

This document replaces the RCR's previous *Guidance on Screening and Symptomatic Breast Imaging, Third Edition* (BFCR(13)5), which is now withdrawn. Significant changes have occurred in screening, the investigation of patients with suspected breast disease and the treatment of patients with breast cancer since the last edition, necessitating a complete revision of the guidance. This now includes recommendations for the investigation of patients presenting with breast symptoms.

1. Investigation of breast symptoms

Diagnostic assessment of patients with breast symptoms is based on 'triple assessment' (clinical assessment, imaging and needle biopsy).¹ The tests used in each case are determined by the symptoms, clinical findings and age of the patient.

Breast imaging facilities should include digital mammography and high frequency ultrasound with probes suitable for breast imaging (12 MHz or more). 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 spectral mammography (CESM) 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.
- Ultrasound is the firstline imaging modality of choice in women aged <40 years and during pregnancy and lactation. Imaging in pregnant and lactating patients is difficult to interpret and a lower threshold should be used for clinical and imaging follow-up and/or biopsy.
- Mammography is the firstline imaging modality of choice in women aged 40 years or over, with the addition of ultrasound as indicated.
- Mammography should be performed on all patients with confirmed malignancy, irrespective of age.
- Mammography should be performed on patients aged 35–39 years with clinically suspicious findings (P4 or P5) and/or ultrasonically 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 digital breast tomosynthesis [DBT]) to help characterise the abnormality.
- DBT or CESM may be used as a firstline investigation instead of mammography in women with clinically suspicious findings, especially in younger women who are more likely to have dense breasts, according to local protocols.
- The level of suspicion for malignancy should be recorded using the British Society of Breast Radiology (BSBR, previously the Royal College of Radiologists Breast Group) imaging classification U1–U5 and M1–M5 (Appendix 1).
- Ultrasound of the axilla should be carried out in all patients when malignancy is suspected or confirmed. If lymph nodes showing abnormal morphology on ultrasound are found, tissue sampling of at least one abnormal node should be performed under ultrasound guidance. There is no agreed threshold for cortical thickness, this varying from 2 to 4 mm between centres, although most use between 2.3 and 3 mm. The threshold should be determined locally and audited to achieve a suitable balance between resultant axillary clearances for low-volume disease without prior surgical sentinel lymph node biopsy (with a low threshold cortical thickness) and excessive numbers of axillary clearances as second operations (with a high threshold cortical thickness). The imaging report should document the number of abnormal nodes.

Needle biopsy

- Clinical and imaging work-up should be completed before needle biopsy is performed.
- Breast needle biopsies should be performed under image guidance – ultrasound or X-ray (stereotaxis or tomosynthesis) guided.
- Core biopsy of both breast lesions and axillary lymph nodes should be performed rather than fine-needle aspiration cytology (FNAC) as it provides higher sensitivity and specificity and also provides important prognostic oncological information (tumour type, grade and receptor status) that can determine treatment.
- Freehand core biopsy is indicated in cases where imaging is normal but there is an indeterminate or suspicious clinical abnormality (P3 or above, confirmed if necessary on senior surgical review).
- Biopsy of lesions within or attached to skin may be carried out using a punch biopsy needle under local anaesthetic (normally by a member of the surgical team). This is particularly suitable for Paget's disease of the nipple and local recurrence within the skin.

Lump/lumpiness/change in texture

- In women aged 40 years and over, mammography and targeted ultrasound should be performed.
- In patients under 40 years with P2 clinical findings, ultrasound should be performed. If this shows normal or benign findings, mammography is unlikely to provide additional diagnostic information.
- Mammography should be performed in women under 40 years for lesions which are suspicious clinically (P4/5) or on ultrasound (U4/5).
- Mammography should be considered in women 35–39 years with P3 clinical findings and normal or indeterminate (U3) ultrasound appearances.
- Most solid breast lesions will require a needle biopsy to complete the triple assessment and establish a diagnosis. Patients with U3–5 findings should undergo needle biopsy.
- In the following cases, clinical and imaging information alone may lead to the diagnosis and needle biopsy may not be required.
 - Presumed fibroadenoma – In patients under 25 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.^{2,3} A higher cut-off age such as 30 years may be used if supported by robust local audit, especially if shear wave elastography shows benign features.
 - Presumed fat necrosis – If P2 and 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 benign 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, then needle 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 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.

Nipple symptoms

- Mammography is indicated in patients 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 alone is not an indication for imaging.
- Persistent focal tenderness should be investigated with ultrasound, plus mammography if aged 40 or over.
- If there are focal clinical signs in the breast these should be imaged as per the guidance above.
- Women aged 40 or over with breast pain/tenderness alone may be offered a mammogram for screening.

Axillary lump (without clinical breast abnormality)

- Mammography should be performed in patients aged 40 and over.
- Axillary ultrasound should be performed together with core biopsy if appropriate. 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 totally fatty.
- If core biopsy demonstrates metastatic carcinoma suggestive of origin from a breast primary and mammography and WBUS are normal, breast magnetic resonance imaging (MRI) is indicated. Computed tomography (CT) is indicated to look for primary malignancy elsewhere if a non-breast primary is suspected.

Breast implants

Imaging is dependent upon whether the clinical features are suggestive of breast cancer or likely to be simply a benign complication of the breast augmentation.

Symptoms and signs suggestive of breast cancer should be investigated with conventional triple assessment. The patient should be counselled about the small risk of damage to implants from mammographic compression and the reduced sensitivity of mammography.⁴ Patients should also be warned about the small risk of implant damage from percutaneous biopsy.

Most benign complications of breast augmentation can be diagnosed specifically with routine imaging. Examples include silicone granulomas and silicone infiltration of lymph nodes which have characteristic ultrasonic appearances. It is important to note that the latter does not indicate the presence of implant rupture when found in isolation and so 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 normally 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 the body,⁵ and therefore aggressive investigation of breast implants and their benign complications is not indicated.

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. Patients 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, specifically querying the diagnosis of BIA-ALCL on the pathology request.

Male breast imaging

Mammography and/or ultrasound should be performed in men with unexplained or suspicious unilateral breast enlargement. Imaging may be used if there is clinical uncertainty in differentiating between true gynaecomastia and fatty breast enlargement.

Unless clinically suspicious (P4 or 5) it is not normally necessary to perform both mammography and ultrasound. Ultrasound is recommended for men below the age of 50, otherwise either ultrasound or bilateral mammography. The 'rolled-nipple' technique may be useful for demonstrating subareolar ducts and confirming the typical appearance of subareolar gynaecomastia.²

Testicular ultrasound scanning should be performed if there is any suspicious finding on testicular clinical examination or raised alpha-fetoprotein (AFP) or β human chorionic gonadotropin (HCG).

Needle core biopsy should be performed following imaging in those patients with uncertain or suspicious radiological findings (P3–5 or U3–5) or where indeterminate clinical findings (P3) are not adequately explained by benign imaging findings. FNAC is not recommended.

2. Population screening

Guidance for radiologists and mammography readers on breast cancer screening of asymptomatic women has been previously published by the NHSBSP.⁶

General principles

The woman 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.⁷

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

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

Although tomosynthesis has been shown to increase cancer detection at screening, it has not been shown to either decrease the number of interval cancers or reduce breast cancer mortality.⁸ It is not recommended for routine screening outside of a clinical trial.

In breasts with implants, supplemental images using the modified compression displacement technique should be employed where possible.⁴

Double reading of screening mammograms is recommended.

Ultrasound on its own is not an effective imaging method for screening. Its use as an adjunct to mammography in screening women with high mammographic density increases breast cancer detection and reduces the rate of interval cancers. Trials looking at the impact of ultrasound screening on mortality have not been performed. Such adjunctive ultrasound has poor specificity and tends to detect low-grade cancers so may increase overdiagnosis. Such screening is not routinely recommended.

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

Mammographic screening of women aged 50–70 years

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 between the ages of 50 and 70 in the UK.

Screening women older than 70 years

There is no evidence from randomised controlled trials to support routine population screening of women over the age of 70, who are more at risk of screening overdiagnosis than younger women. The results of the UK age extension trial screening women aged 70–73 (and 47–49) taking place in England and Wales are not expected for several years.⁹ 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 if they so wish.

Screening women between the ages of 40 and 49 years

Randomised control trials have shown a significant mortality reduction in women aged 40–49 from mammographic screening. This mortality reduction is less than that seen when screening older women. Screening women of this age requires more frequent mammography and is less specific than screening in older women. Screening women at this age does not increase overdiagnosis compared with women commencing screening aged 50.

Screening women under the age of 40 years

There is no evidence to support screening of women <40 years old who are not at increased risk from breast cancer.

3. Higher risk and risk-adapted screening

There is increasing interest in providing screening tailored to individuals' risk of breast cancer, using the most appropriate screening modality according to the age of the patient, her breast cancer risk and the composition of the breasts. Theoretically this allows screening resources to be used more effectively and efficiently, focusing on women who are most likely to benefit and reducing the risk of causing harm (through false positive screening, overdiagnosis/overtreatment and radiation-induced cancer) to women at lower risk. At present, there is some stratification based on risk, largely in women who self-refer with a known family history of breast cancer and in those identified as having a gene mutation or previous radiotherapy to sites above the diaphragm involving breast tissue. However, this is an area of active research and is likely to develop further over the next few years.

Currently many women who are known to be at moderate or greater risk of breast cancer are offered additional screening. Those identified in the eligible age group who are in the highest risk category (now known as 'very high-risk', to distinguish it from the 'high-risk' group defined by the National Institute for Health and Care Excellence [NICE]) are offered screening in the NHSBSP. Women in high- and moderate-risk groups as defined by NICE may be offered screening outside the NHSBSP.

The NHSBSP guidance for screening very high-risk women is being revised, with publication expected late in 2019.

In addition to the factors mentioned above, breast density is a major risk factor, women with dense breasts having a four or fivefold greater risk of developing breast cancer than those with fatty breasts. Some of the risk calculators, such as Tyrer-Cuzick version 8, now incorporate breast density in addition to personal factors and family history, and it is therefore recommended that breast density is stated on the surveillance mammography report for higher risk women using an appropriate and available method (automated, visual analogue scale or BI-RADS).

Screening women at very high risk

There are a number of gene mutations which confer a substantially increased lifetime risk of breast cancer (over 80% in some), including *BRCA1*, *BRCA2* and *TP53*. In addition, prior irradiation of breast tissue (typically for the treatment of Hodgkin lymphoma) confers a substantial risk of cancer induction in the irradiated breast.

Women falling into these categories and in the specified age range are eligible for additional screening with annual mammography and/or annual MRI within the NHSBSP.¹⁰

Screening women at high and moderate risk

NICE defines the risk groups as follows:

Risk group	Lifetime risk	Ten-year risk (ages 40–50)
High risk	≥30%	>8%
Moderate risk	≥17%	3–8%
Average risk	<17%	<3%

High risk

30–39 years – consider offering annual mammography.

40–59 years – offer annual mammography.

Moderate risk

40–49 years – offer annual mammography.

50–59 years – consider offering annual mammography.

Mammography should be avoided in TP53 mutation carriers and A-T (ataxia telangiectasia) homozygotes.

Screening of women without a proven *BRCA* or *TP53* gene mutation but with family members carrying such mutations are detailed in NICE clinical guideline 164.¹¹

MRI

Surveillance MRI (whether performed inside or outside the NHSBSP) should be performed and reported to NHSBSP standards.¹²

Surveillance ultrasound

A number of studies have demonstrated a significant incremental cancer detection rate with the addition of bilateral whole breast ultrasound to bilateral digital mammography, especially in women with dense breasts. However, this is generally at the expense of a higher false positive rate and higher biopsy rate and lower positive predictive value for recall and biopsy.¹³ It should be offered when MRI would normally be offered but the patient is unable or unwilling to undergo MRI and may be considered in women at high risk with very dense breasts. If it is offered as a screening test then the woman should be informed of the greater risk of a false positive screen.

Surveillance of women with both a personal and family history of breast cancer

Recommendations are included in NICE clinical guideline 164.¹¹

4. Screening assessment

All women recalled following an abnormal screening mammogram, screening breast MRI or recalled due to symptoms will undergo triple assessment at second stage screening.¹⁴

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 X-rays and/or ultrasound), clinical examination and tissue sampling if appropriate.

Further X-rays include additional mammographic views such as extended, compression and magnification views. Digital breast tomosynthesis (DBT) with NHSBSP-approved equipment may be used in second stage screening assessment but not as a firstline screening tool within the NHSBSP outside a clinical trial. Studies have shown that DBT can reduce the need for further additional views and increase the confidence of the clinician/consultant radiographer in interpreting the mammographic abnormality as being benign or malignant.¹⁵

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

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

Tissue sampling can 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. Conventional 14-gauge core needle biopsy is recommended for axillary lymph nodes.¹⁶ 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 clinician/consultant radiographer to confirm agreement with the assessment outcome and this should be documented prior to final discharge of the client.

5. Staging of breast cancer

The importance of the biology of the disease is now recognised. In the eighth edition of the American Joint Committee on Cancer (AJCC) cancer staging manual,¹⁷ anatomical TNM has altered little but prognostic factors are now incorporated, including grade, receptor status and multigene panels if available. For example, a T2 N0 ER positive HER2-negative tumour with a 21-gene (Oncotype Dx) recurrence score <11 is placed in the same prognostic category as a T1 a/b N0 M0 tumour.

Loco-regional staging

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

DBT may have incremental detection rates over full-field digital mammography (FFDM) for uni- and multifocal disease and has equivalent accuracy to FFDM combined with compression mammographic views at imaging assessment.¹⁸⁻²⁰

CESM has comparable accuracy to dynamic contrast-enhanced MRI for T-staging and assessing for multiple primary tumour foci.²¹⁻²³

MRI is indicated:²⁴

1. If breast conservation is being considered and sizing is uncertain on clinical evaluation and conventional imaging (mammography 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)*^{25,26}
 3. In mammographically occult tumours
 4. Where there is suspicion of multifocal disease unconfirmed on conventional imaging
 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.
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*MRI to screen the contralateral breast in women with an invasive cancer with a lobular component is not recommended if mastectomy for the known cancer is planned (or has been performed).^{27,28}

If gadolinium administration is contra-indicated consider the combination of T2-weighted and diffusion-weighted imaging (DWI).²⁹

Axillary ultrasound assesses nodal disease burden; documentation of the number of abnormal nodes demonstrated is good practice. The infraclavicular and supraclavicular fossae should also be scanned if there is a heavy nodal burden (>four obviously abnormal nodes). Core biopsy sampling is more sensitive than FNAC.¹⁶

Staging for distant metastatic disease

Metastatic disease at presentation occurs in only 4–6% of patients; whole-body staging is not required in the vast majority of cases.

Indications:

1. T3 and T4 primary cancers
2. ≥ 4 abnormal nodes at axillary ultrasound or ≥ 4 macrometastatic nodes at axillary surgery
3. If symptoms raise the suspicion of metastatic disease.

At present, there is no evidence base for carrying out staging prior to neoadjuvant chemotherapy in $\leq T2$ tumours with $\leq N1$ disease.³⁰

Contrast-enhanced CT of the chest, abdomen and pelvis, incorporating the supraclavicular fossae and proximal femora, is the modality of choice in most cases and is more accurate than conventional chest radiography with liver ultrasound and Tc99m-methylene diphosphonate (MDP) bone scintigraphy. Bone scintigraphy is not routinely indicated in addition to CT in the absence of bone symptoms.^{31–33}

Fluorodeoxyglucose (FDG) positron emission tomography–computed tomography (PET-CT) has an incremental detection rate of distant metastases over CT of approximately 25% in inflammatory breast cancer and thus should be considered for this indication.

FDG PET-CT is also indicated in problem-solving when other imaging modalities are indeterminate.³⁴

Whole-body MRI may be utilised in staging and is valuable in further evaluating cases which are equivocal on other imaging modalities.³⁵ Avoiding the use of ionising radiation and the need for administration of intravenous contrast agents, WB-MRI represents the imaging technique of choice for systemic staging in pregnant women with breast cancer.³⁶

6. Monitoring of response to neoadjuvant drug treatment

The minimum imaging for treatment monitoring is digital mammography and breast ultrasound at baseline and end of treatment.

In most cases insertion of a tissue marker is recommended prior to treatment. This is not mandatory in women in whom the decision to perform mastectomy has already been taken (unless required to aid subsequent histopathological location of the tumour bed) or where a substantial treatment response is not likely, as indicated by immunophenotype and imaging phenotype.

Tissue marker insertion into a biopsied axillary node is indicated where local policy is to perform post-treatment image-guided axillary node localisation and targeted node dissection.

MRI is the most accurate imaging technique for baseline local staging and correlates best with pathological findings post-treatment.^{37,38} It is recommended at baseline and end of treatment to aid surgical planning. The use of an interim scan (after two or three cycles) aids prediction of response and will become of increasing importance in response-adapted therapy. Diffusion-weighted imaging (DWI) has the potential to be of use if protocols are standardised.³⁹

Repeat mammography and ultrasound at the end of treatment may not be necessary if MRI is performed.

CESM has a small evidence base in response assessment that suggests that it is likely to have a similar accuracy to MRI.

If there is residual mammographic microcalcification (especially in HER2-positive disease) consider re-biopsy of the tumour bed to ascertain the presence of viable ductal carcinoma in situ (DCIS) if surgical management would be altered.

7. Imaging follow-up after breast cancer treatment

Women 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 in order to improve survival and quality of life.

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%.⁴⁰ Women with mammographically-detected IBTR have better survival rates than those with IBTR detected by clinical examination.

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.⁴¹

Women should be offered annual mammography for five years or until age 50, whichever comes later. The clinical utility and cost-effectiveness of mammography more frequently than three-yearly (as offered by the NHSBSP) beyond that time is unknown and is the subject of current research (the Mammo-50 trial).

The evidence for early detection influencing the outcome decreases and the risk of overdiagnosis increases with age. Surveillance of the treated breast should not be undertaken (or should cease) if it is considered that there is unlikely to be a survival benefit of detecting an asymptomatic recurrence or second breast cancer. Annual mammographic surveillance solely of the contralateral breast is not recommended after the age of 75 years, although women can self-refer for three-yearly mammography in the NHSBSP if they so wish.

Ipsilateral imaging surveillance after mastectomy and reconstruction

Routine imaging of asymptomatic mastectomy flaps with mammography and/or ultrasound is not recommended. There is insufficient evidence to recommend routine mammographic surveillance of women following autologous breast reconstruction, but it may be justified in women at high risk of local recurrence (for example, those with extensive high grade DCIS close to a margin).

Surveillance using other imaging modalities

The evidence for using DBT in follow-up is sparse and it is not recommended.

Early evidence suggests that MRI is the most accurate test for detecting ipsilateral and contralateral breast cancer in previously treated primary cancer but further studies to determine its clinical utility and cost-effectiveness are needed.⁴¹ Its use may be considered in young women, women with dense breasts and women with mammographically occult breast cancers.

Whole-breast ultrasound is not recommended for routine surveillance following primary breast cancer.

Imaging surveillance of the ipsilateral axilla

Routine ultrasound surveillance of the asymptomatic ipsilateral axilla following breast cancer treatment is not recommended as the early detection of axillary recurrence has not been shown to improve outcomes.

Imaging surveillance in women in higher risk groups

Women already in higher risk groups that qualify for more frequent mammographic and/or MRI screening should continue on the same higher risk protocol after treatment for breast cancer.¹¹

Imaging surveillance in pregnancy and lactation

Mammography may be safely performed during pregnancy with a negligible radiation risk to the fetus.⁴² Mammographic breast density increases during pregnancy and lactation, and women should be made aware that the effectiveness of mammography is reduced and the radiation dose to the breast is increased during this time. Women undergoing mammography during lactation should be advised to breastfeed or pump milk prior to the examination in an attempt to reduce breast density.

MRI sensitivity may be reduced by a high level of background parenchymal enhancement in pregnancy and lactation. Contrast-enhanced MR imaging in pregnancy should be limited. Each case should be reviewed carefully and a macrocyclic gadolinium-based contrast agent administered only when there is a potential significant benefit to the patient

that outweighs the possible risk of exposure of the fetus to free gadolinium ions.⁴³ MRI surveillance during pregnancy is not recommended but may be considered in lactating women at high risk who are informed of the limitations of the technique. There is negligible excretion of gadolinium into breast milk.⁴⁴

Whole breast ultrasound surveillance during pregnancy and lactation has a high false-positive rate and is not recommended.

In women who opt to postpone surveillance during pregnancy and lactation, this should be resumed approximately three months after cessation of lactation to allow the breast parenchyma to return to baseline density.

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.⁴⁵ Men should be offered the same annual mammographic surveillance of residual breast tissue following primary breast cancer as female patients.

Symptomatic presentation after breast cancer treatment

Patients who develop potentially related symptoms following treatment of breast cancer should be offered rapid access to triple assessment including mammography, ultrasound and biopsy. MRI may be useful in suspected recurrence where conventional triple assessment has failed to provide a definitive diagnosis.

8. Assessment and follow-up of metastatic disease

Visceral disease

Contrast-enhanced CT of the thorax, abdomen and pelvis is usually sufficient. FDG PET-CT or tailored MRI can be used for problem-solving, for example following equivocal results of CT.³⁴

Skeletal disease

MDP bone scintigraphy may be used in the initial diagnosis of symptomatic bony metastatic disease but does not perform well in follow-up and for monitoring treatment response. Consider DWIBS or FDG PET-CT.

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.³⁴

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

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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.⁴⁶ 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) or MRI (magnetic resonance imaging).

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.

Axilla

With the now widespread use of axillary ultrasound in patients with suspected or established breast cancer, 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.
A3 Indeterminate 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 breast malignancy (M3 and/or U3), biopsy of A3 nodes may only be necessary if breast malignancy is confirmed.

Appendix 2. Breast MRI protocol and reporting guidelines

Equipment and protocol

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

The following sequences are recommended:

High resolution T2 +/- fat saturation

Diffusion-weighted imaging (DWI). Two b values are adequate:

b50 (to remove intravoxel incoherent motion)

b850-1000 (according to magnet strength)

consider calculated high b value (b1500 or b2000)

Dynamic contrast-enhanced – each acquisition time period not >60 seconds (preferably not >45 seconds), out to five minutes

High resolution 3D T1W fat suppressed GRE with isotropic voxels.

Reporting

The use of consistent unified terminology using BI-RADS lexicon fifth edition is suggested, although the final score should normally be using the UK system (Appendix 1).⁴⁷ It is useful to comment on breast composition and level of background parenchymal enhancement.

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.^{48,49} The calculations were updated from the NHSBSP Report 54 to take into account changes in current practice:⁵⁰

- Mammography systems now use digital mammography, rather than film-screen, with different X-ray target and filter materials; this has reduced the average breast dose.
- The average mean glandular dose is now 3mGy per two-view examination, which was determined by Young and Oduko in a national survey of radiation dose in digital mammography.⁵¹
- Recent publications have provided updated radiation risk coefficients from those used in the NHSBSP Report 54. The ICRP103 model was used in the work by Warren *et al.*^{49,52}
- Assumptions about mortality due to breast cancer outside screening have also changed due to improved treatments. In the literature, the mortality reduction in the population invited to screening averaged 20%, with a range from 15 to 30%. This value and range were used in the work by Warren *et al.*

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. 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.⁴⁹ 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 200:1.⁴⁸

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.⁵³ 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.⁵⁴ 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.¹⁰

Appendix 4. Professional standards

Radiologists involved in symptomatic breast imaging

Radiologists with a special interest in symptomatic breast imaging should:

- Assume responsibility for the provision and quality of imaging in symptomatic breast services.
- Have satisfied RCR training requirements, achieving a minimum competence of level 1, preferably level 2, breast imaging training as detailed in the RCR training curriculum 2016.
- Be personally involved in the interpretation and reporting of a minimum of 500 symptomatic mammograms per annum.
- Be part of a multidisciplinary team associated with a designated specialist breast unit.
- Have appropriate contracted time (identified in a personal job plan) specifically designated for participation in multidisciplinary breast assessment. It is anticipated that a specialist breast radiologist will require two, and preferably three, programmed activities dedicated to breast assessment. This should include participation in diagnostic breast clinics organised in a manner which ensures that direct and timely consultation with the other members of the clinical team can take place.
- Participate in regular multidisciplinary clinical management meetings. Preparation for, and attendance at, these meetings may count towards the dedicated programmed activities specified above.
- Ideally also participate in the NHSBSP.
- Be proficient in the following tasks:
 - Interpretation of mammograms and appropriately requested additional mammographic views.
 - Clinical history and examination as appropriate.
 - Ultrasound of the breast and axilla.
 - Needle biopsy of the breast – core biopsy, and preferably also vacuum-assisted core biopsy, guided by ultrasound and preferably also stereotaxis.
 - Needle biopsy of the axilla – core biopsy guided by ultrasound.
 - Localisation of impalpable breast lesions by ultrasound and/or stereotaxis.
 - Mammography and breast ultrasound reporting should use recognised and recommended descriptive terminology and should include details of size, site and nature of any abnormality with an opinion as to the likely diagnoses and recommendations for any further diagnostic procedure or intervention.
- Participate in a personal breast imaging audit and multidisciplinary breast service audit.
- Comply with the requirements for training and continuing professional development (CPD) as prescribed by the RCR and ensure that this includes appropriate breast imaging content (<https://www.rcr.ac.uk/clinical-radiology/cpd/cpd-faqs>).

Radiologists involved in the NHSBSP and other breast screening

Professional standards for radiologists involved in the NHSBSP have been previously established (*Quality Assurance Guidelines for Breast Cancer Screening Radiology, NHSBSP Publication No 59, March 2011*).

The screening and symptomatic breast imaging guidelines are compared and summarised below:

Breast screening	Symptomatic
In order to maintain expertise each radiologist involved in breast screening should fulfil the following criteria:	In order to maintain expertise each radiologist involved in symptomatic breast work should fulfil the following criteria:
a. Be employed for a minimum of three programmed activities dedicated to direct clinical care in breast imaging	a. Be employed for a minimum of two programmed activities dedicated to direct clinical care in breast imaging with time specifically allocated for multidisciplinary breast assessment
b. Undertake a minimum of 5,000 screening and/or symptomatic cases per annum	b. Undertake a minimum of 500 symptomatic cases per annum
In addition, each radiologist should fulfil the following criteria:	In addition, each radiologist should fulfil the following criteria:
a. Have attended an RCR-approved course	a. Have attended an RCR-approved course
b. Be normally involved and skilled in all aspects of breast screening, including mammography reading, screening assessment and MDT meetings at which screening cases are discussed	b. Be normally involved and skilled in all aspects of symptomatic breast imaging, including mammography interpretation, breast assessment and MDT meetings at which symptomatic cases are discussed
c. Attend regular multidisciplinary clinical management meetings	c. Attend regular multidisciplinary clinical management meetings
d. Comply with RCR requirements for training and CPD	d. Comply with RCR requirements for training and CPD
e. Have access to pathology and surgical follow-up data	e. Have access to pathology and surgical follow-up data
f. Undertake formal audits of performance	f. Undertake formal audits of performance
g. Participate in an approved radiologists' performance quality assurance scheme for mammography	

It would be advantageous also to meet the following criteria:	It would be advantageous also to meet the following criteria:
a. Be involved with symptomatic breast work	a. Be involved with breast screening
b. Have skills in clinical examination	b. Have skills in clinical examination
c. Have training in communication and 'breaking bad news' as required by the cancer peer review standards	c. Have training in communication and 'breaking bad news' as required by the cancer peer review standards
	d. Participate in an approved radiologists' performance quality assurance scheme for mammography

Terminology

BIA-ALCL	breast implant-associated anaplastic large cell lymphoma
BSBR	British Society of Breast Radiology
CC	craniocaudal
CESM	contrast-enhanced spectral mammography
CPD	continuing professional development
CT	computed tomography
DBT	digital breast tomosynthesis
DWI	diffusion-weighted imaging
DWIBS	diffusion-weighted imaging with background-body-signal-suppression
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
PET-CT	positron emission tomography - computed tomography
NHSBSP	National Health Service Breast Screening Programme
US	ultrasound
WBUS	whole breast ultrasound

Acknowledgements

The following individuals contributed to the writing of these guidelines:

Dr Megan Bydder, Manchester
Dr Eleanor Cornford, Cheltenham
Dr Julie Cox, Sunderland
Dr Hilary Dobson, Glasgow
Professor Andy Evans, Dundee
Dr Simon Lowes, Gateshead
Professor Iain Lyburn, Cheltenham
Dr Anthony Maxwell, Manchester (editor)
Dr Jonathan Nash, Portsmouth
Dr Jenny Oduko, Guildford
Dr Alan Redman, Gateshead
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The Royal College of Radiologists. *Guidance on screening and symptomatic breast imaging, fourth edition*. London: The Royal College of Radiologists, 2019.

Ref No. BFCR(19)9

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Corrected edition 29 November 2019.

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