

Guidance on screening and symptomatic breast imaging

Third edition

Faculty of Clinical Radiology

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Foreword

Following publication of two previous editions in 1999 and 2003, the third edition of *Guidance on Screening and Symptomatic Breast Imaging* reflects the continuing demand for breast imaging as a result of changes in the provision of cancer services in the NHS and the widespread development of specialist breast clinics around the UK. This document is an update of the previous RCR's *Guidance on Screening and Symptomatic Breast Imaging, Second Edition* (BFCR(03)2), which is now withdrawn, but does not include guidance on topics already included in the *Best practice diagnostic guidelines for patients presenting with breast symptoms*.¹

The document is provided for radiologists and other members of breast teams providing diagnostic, treatment and follow-up services for patients with symptomatic breast problems. Guidance on the role of imaging in breast cancer screening is also included.

I am extremely grateful to Dr Andrew Evans for his help in revising and updating this guidance.

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Introduction

The majority of women presenting with breast symptoms first consult with their general practitioner (GP). Most of these women can be managed, at least initially, by their GP. Guidelines regarding those patients who should be referred for a specialist opinion and how they should be investigated and managed have been published in *Best practice diagnostic guidelines for patients presenting with breast symptoms*.¹ These guidelines, published in 2010, were produced in consultation with many professional groups,

including The Royal College of Radiologists' Breast Group (now the British Society of Breast Radiology). This document is an update of the previous RCR's *Guidance on Screening and Symptomatic Breast Imaging, Second Edition*, which is now withdrawn, but does not include guidance on topics already included in the *Best practice diagnostic guidelines for patients presenting with breast symptoms*.¹

Population breast cancer screening of asymptomatic women

Guidance for radiologists and mammography readers on breast cancer screening has been previously published by the NHS Breast Screening Programme (NHSBSP).²

General principles

The technical quality of all screening mammography should be at least to the standards required by the NHSBSP.³

- Radiographers performing screening mammography should hold, or be training for, the College of Radiographers' Postgraduate Award in Mammography Practice.
- Screening mammography should be interpreted by readers who satisfy the professional standards required by the NHSBSP.
- Ultrasound on its own is not an effective imaging method for routine screening. Its use as an adjunct to mammography in screening women with high mammographic density is associated with an increase in detection of early breast cancer and a reduction in the interval cancer rate but has a poor specificity. It is not recommended as a routine procedure.⁴
- Screening, wherever performed, should always include formally agreed mechanisms for referral, without delay, of women with screen-detected abnormalities to a specialist breast team.
- The woman should be provided with information detailing the risks and benefits of screening mammography before the examination.

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 69 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. Analysis of screening lead times and interval cancer rates suggest a two-year interval would be more appropriate in this age group.^{5–8} A trial of screening women aged 47–49 and 70–73 is occurring in England and Wales.⁹

Two-view mammography (mediolateral oblique and craniocaudal projections of each breast) is required at each attendance. Digital mammography is recommended over film screen mammography, particularly in younger women, in view of its improved cancer detection performance. Double reading is recommended.

Screening women older than 70 years

The UK age extension trial will provide data which will help assess the value of screening women aged 70–73.⁹ There is currently no evidence from randomised, controlled trials to support routine screening of women aged over 70 years. Screening these older women is controversial given the increased risk of harm from over-diagnosis (the diagnosis and treatment of cancers that would not cause harm if undetected).

Screening women between the ages of 40 and 49 years

Individual women in this age group who seek or are referred for mammographic screening should be made fully aware of the risks as well as the possible benefits before being screened. Meta-analysis of randomised, controlled trials (including the UK age trial) of screening women in this age group have shown a mortality benefit of 17%.¹⁰ This is somewhat less than that seen when screening women aged 50–69. Mammographic sensitivity and specificity is poorer in young women compared to older women and cancer lead times are shorter. Those studies demonstrating the largest mortality reductions have used short screening intervals (12 to 18 months) and multiple screening rounds (five or more). The low breast cancer incidence coupled with the high percentage of female deaths due to breast cancer in this age group provokes debate regarding the importance of screening younger women.

Two-view digital mammography at each screening visit is recommended. Screening more frequently than every year is not recommended.

Screening women under the age of 40 years

There is no evidence of a mortality benefit from mammographic screening of women under the age of 35 years. There is also a greater risk of radiation-

induced breast cancer from the use of diagnostic X-ray mammography in young women. For these reasons, routine screening of women in this age group in the absence of significant breast cancer risk factors is not recommended unless as part of a formal trial. MRI screening of women at high familial risk of breast cancer detects additional small node negative cancers compared with screening with mammography. The effect of such screening on breast cancer mortality is unknown.

Assessment of screen-detected abnormalities

In the NHSBSP, it is routine for all screen-detected abnormalities to be assessed by a multidisciplinary team of breast specialists, and the NHSBSP has the responsibility to carry out the tests required to confirm definitively the presence or absence of malignancy. All screening providers should ensure an assessment service operates to at least the same standard as the NHSBSP.

Screening in the private sector

A significant amount of mammographic screening occurs outside the NHS. Radiologists involved in non-NHS screening should satisfy the same professional standards that apply to those working in the NHSBSP (Appendix 1) and should ensure that all further assessment procedures are to the same standard as apply in the NHSBSP. Further assessment procedures should be discussed and agreed with the patient before screening is carried out.

Previous benign breast biopsy

In most cases (70%) a history of previous benign breast biopsy carries no increased risk of subsequent development of breast cancer. However, a past history of biopsy showing atypical

hyperplasias, particularly atypical lobular hyperplasia, is associated with an increased risk of breast cancer. This risk is increased further if there is also a family history of breast cancer in a first-degree relative.¹¹ There is no evidence that screening of women with epithelial hyperplasia offers any mortality benefit. However, it is accepted practice to offer screening to women in this risk category, especially if they are below the age where women are offered routine screening. Screening should be carried out in accordance with NHSBSP standards.

Mammography in women receiving hormone replacement therapy (HRT)

Women using long-term hormone replacement therapy (particularly combined oestrogen and progesterone) are at increased risk of breast cancer and breast cancer death.¹² This effect is seen in pre- and post-menopausal women.¹³ The effect is largely resolved within two years after discontinuing HRT.¹⁴ However, both sensitivity and specificity of mammography are reduced in women taking HRT.

'Baseline' mammography is not routinely required prior to commencing HRT. Women receiving HRT over the age of 50 years are offered screening every three years as part of the NHSBSP as a matter of routine. In this age group, there is no evidence to support more frequent screening. For women under the age of 50 years, the effectiveness of screening may be reduced but screening may be considered for women with >5 years of use.

The use of imaging in the follow-up of patients with breast cancer

Women in higher risk groups that qualify for more frequent screening and screening with MRI should continue with on the same higher risk protocol after treatment for breast cancer; for example, BRCA gene carriers should continue with screening MRI.

Imaging of the opposite breast after treatment for breast cancer

Women who have had breast cancer have an increased risk of a second primary breast cancer for at least 20 years compared to the general population. Patients with metachronous contralateral breast cancers (MCBCs) detected by routine mammography have better survival rates than patients with MCBCs detected by other means.¹⁵ Women with a history of breast cancer aged under 50 should have an annual mammography until the age of 50. The required frequency after the age of 50 is not clear but mammography is commonly performed every two or three years. The age at which to stop screening is also unclear. However, as the evidence for early detection influencing outcome reduces and the risk of over-diagnosis increases with age, routine mammographic surveillance of the contralateral breast is not recommended after the age of 75 years.

Imaging of the treated breast following surgery with breast conservation

Women who have had breast cancer treated by breast conserving surgery are at long-term risk of local recurrence. Mammographically detected local recurrences or those detected by women themselves have better survival than those detected by clinical examination.¹⁶ The sensitivity of routine surveillance mammography for the detection of ipsilateral breast tumour recurrence ranges from 64% to 67% with a specificity from 85% to 97%.¹⁷ Women aged under 50 who have had breast cancer treated by breast conserving surgery should have annual mammography until

50 years of age. The required frequency after the age of 50 is not clear but mammography is commonly performed every one to three years. The age at which screening should cease is also unclear. It is recommended that ipsilateral screening should cease when it is considered that co-morbidities would make the detection of an asymptomatic recurrence unhelpful.

Imaging of mastectomy flaps and ipsilateral axilla

Routine imaging of asymptomatic mastectomy flaps with mammography and/or ultrasound is not recommended. Routine ultrasound of the asymptomatic ipsilateral axilla following treatment for breast cancer is not recommended as early detection of axillary recurrence has not been shown improve outcomes.

Imaging of autologous breast reconstruction

Women who have been treated with therapeutic mastoplasty should undergo the same follow-up imaging as women who have had breast-conserving surgery. Impalpable local recurrence following autologous breast reconstructions are rare.¹⁸ Mammographic surveillance of these is only justified if a woman is thought to be at high risk of local recurrence.

Once an abnormality is detected, either clinically or radiologically, rapid access is required for imaging and biopsy. MRI may be useful in patients with suspected recurrences in whom conventional triple assessment has failed to provide a firm diagnosis.

Image-guided biopsy of the breast and axilla

Guidelines regarding the performance of these techniques are described in *Clinical Guidelines for Breast Cancer Screening Assessment* published by the NHSBSP.³

Supplementary imaging techniques

MRI

Breast MRI has advantages such as high sensitivity for invasive (but less so for in situ) disease and does not use ionising radiation. It may be useful in local staging prior to breast conservation in women with invasive lobular cancer, dense breasts and when there is discordance between assessments of tumour size using different methods.^{19,20} MRI is also useful for monitoring the response to neoadjuvant chemotherapy²¹ and in detecting occult primary tumours in women presenting with adenocarcinoma in axillary lymph nodes. MRI is the modality of choice to assess the integrity of breast implants.²² MRI screening can find small mammographically occult cancers with an acceptable specificity in women with a high-risk family history.²³ Guidelines on the use of MRI as part of pre-treatment assessment have been included in the 2009 National Institute for Health and Clinical Excellence (NICE) guidelines on *Early and Locally Advanced Breast Cancer*.²⁴ Guidelines on the wider use of breast MRI have been published by the European Society of Breast Cancer Specialists (EUSOMA) in 2010²⁵ and by European Society of Breast Imaging (EUSOBI) in 2008.²⁶

Breast-specific gamma imaging

Breast-specific gamma imaging has been shown in a number of studies to have sensitivity for breast cancer detection approaching that of MRI.²⁷ Widespread introduction has not occurred as specific indications have not yet been defined and there are serious concerns regarding the very high radiation dose currently used for these examinations.²⁸ Its routine use is not recommended.

Thermography

Currently there is not sufficient evidence to support the use of thermography in breast cancer screening, nor is there sufficient evidence to show that thermography provides benefit to patients as an adjunctive tool to mammography or to suspicious clinical findings in diagnosing breast cancer.²⁹ The use of this technique is not endorsed or recommended in these guidelines.

Shear wave ultrasound elastography

Shear wave elastography is a reproducible, quantitative adjunct to greyscale ultrasound analysis of breast masses. It appears in early studies to show promise in improving either the specificity and sensitivity of breast ultrasound.^{30,31} Further UK-based multi-centre studies are required before its use in routine breast practice can be recommended.

Screening for metastatic disease

The incidence of metastatic disease in patients with early-stage breast cancer is extremely low (under 2%)³² and whole-body screening for metastases in this group is not recommended. The likelihood of metastatic disease in patients with N2 disease (more than four nodes positive) or a T4 tumour is sufficiently high to justify whole-body staging. The frequency of metastatic disease in women with local and regional recurrence also justifies screening for metastases. In asymptomatic patients, contrast-enhanced CT of the chest abdomen and pelvis can obviate the need for isotope bone scan.³³ In the special case of inflammatory breast cancer consideration may be given to PET-CT because of its incremental increased sensitivity for the diagnosis of metastatic disease compared with conventional CT.³⁴

Radiation risks in mammography

A review, NHSBSP Report 54, undertaken on behalf of the NHSBSP³⁵ has considered the radiation risk associated with breast screening. It is recognised that there are large uncertainties in low-dose cancer risk estimates and, in its 2000 report,³⁶ the United Nations Scientific Committee on the Effects of Atomic Radiation (UNSCEAR) stated that the uncertainty in risks for solid cancers overall, following acute high exposures, may be a factor of around two, higher or lower, and that a further factor of two, higher or lower, may apply when estimating risks from chronic or low doses. Recently the Health Protection Agency (HPA) published a report from its Advisory Group on Ionising Radiation (AGIR) on the *Risk of solid cancers following radiation exposure: estimates for the UK population*.³⁷ This report included a review of the evidence for

breast cancer induction following radiation exposure giving risk factors as summarised in Table 1. Also shown in Table 1 are the comparable cancer induction rates assumed in NHSBSP Report 54. The excess absolute risk (EAR) and the excess relative risk models (ERR) are alternative ways of interpreting the data and together yield a range for the expected induction rate. The induction rates assumed in NHSBSP Report 54 are within the range of those provided in HPA 2011. It is expected that NHSBSP Report 54 will be revised in 2013 to take account of this new guidance on risk factors as well as changes in radiation dose due to the introduction of digital mammography and changes in breast cancer mortality. However, the impact of these changes is expected to be relatively modest compared to the uncertainties in the underlying risk factors.

Table 1. Comparison of cancer induction rates in two reports for 1,000 females in the UK population following mammography screening where the breast dose per examination (2 views) is 4.5 mSv

Report	Model	Age at exposure (years)						
		35–39	40–44	50–54	60–64	70–74	Annual 40–47	Every 3 years for 47–73
HPA 2011 ³⁷	ERR	0.18	0.15	0.10	0.06	0.03	1.10	0.60
HPA 2011 ³⁷	EAR	0.12	0.09	0.05	0.03	0.01	0.61	0.28
NHSBSP 54 ³⁵	–	–	–	0.06	0.04	0.02	–	–

The NHSBSP Report 54 reached the following conclusions.

- The risk of a radiation-induced cancer for a woman attending mammographic screening (two views) by the NHSBSP is about 1 in 20,000 per visit.
- One hundred and fifty-four cancers are detected by the NHSBSP for every cancer induced.
- The natural incidence of breast cancer in the UK population may be increased by 0.2% due to radiation-induced cancers.
- Screening with the NHSBSP regime of two views every three years from age 50 to 70 years is justified in radiation protection terms

with 80 lives saved for every life lost due to radiation-induced cancers. This ratio depends upon the mortality reduction achieved by the screening programme and it falls to 53:1 if the reduction is 25% for screened women and rises to 106:1 if the mortality reduction is 40%.

- For the very small proportion of women who receive the highest radiation doses, the benefit will exceed the risk by about 16:1.

Law, Faulkner and Young (2007)³⁸ considered the risk factors for the induction of breast cancer by X-rays and their implications for breast screening. Having reviewed the risk factors and the underlying assumptions involved, they calculated cancer detection/induction ratios, as an index of benefit/risk, for screening age women

and for younger women with and without a family history of breast cancer. They concluded that in the NHSBSP benefit exceeds radiation risk regardless of which radiation risk factors were adopted. At younger ages, there was little if any risk of detriment exceeding benefit down to age 40 years. Annual two-view screening should not be considered below the age of 35 for women with no family history, and even for those who do have such a history, it should only be considered if the index patient was diagnosed below the age of 40 years.

The typical dose assumed in the above risk calculations is a mean glandular dose of 4.5 mGy for a two-view screening examination of both breasts. This is based on radiation doses

reported in UK screening by Young and Burch.³⁹ Young⁴⁰ (2002) updated this dose data and showed that the radiation doses in screening were relatively unaffected by the age of the woman at screening.

Faulkner (2007)⁴¹ reviewed the extent to which women with a genetic disposition to breast cancer (that is, BRCA1 and BRCA2 carriers) were at additional risk of cancer induction due to mammography. He concluded that for such women the radiation risk factor estimated using the ERR model would be higher than that for the general population; however, the benefit/risk ratio would remain constant as both the incidence of breast cancer and the radiation risk would increase by the same factor.

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Appendix 1. 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 2010
- 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 may count towards the dedicated programmed activities specified above to a maximum of 0.5 PA
- Ideally also participate in the NHSBSP
- Be proficient at 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/or vacuum-assisted core biopsy (VACB) guided by ultrasound or stereotaxis
 - Needle biopsy of the axilla – core biopsy or fine needle aspiration (FNA) guided by ultrasound and localisation of impalpable breast lesions
 - Mammography and breast ultrasound reporting should use recognised and recommended descriptive terminology and include details of site, imaging size and nature of any abnormality with an opinion as to the likely diagnoses and recommendations for any further diagnostic procedure or intervention
- Participate in personal breast imaging audit and multidisciplinary breast service audit
- Comply with the requirements for training and continuing professional development (CPD) as prescribed by The Royal College of Radiologists and ensure that this includes an appropriate breast imaging content.

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 professional guidelines are compared and summarised below.

Breast screening

In order to gain and maintain expertise, each radiologist involved in breast screening should fulfil the following criteria:

- a. Be employed for a minimum of three programmed activities dedicated to direct clinical care in breast imaging
- b. Undertake a minimum of 5,000 screening and/or symptomatic cases a year.

In addition, each radiologist should fulfil the following criteria:

- 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
- c. Attend regular multidisciplinary clinical management meetings
- d. Comply with RCR requirements for training and continuing professional development (CPD)
- e. Have access to pathology and/or surgical follow-up data
- f. Undertake formal audit of performance
- g. Participate in an approved radiologists' performance quality assurance scheme for mammography.

It would be advantageous also to meet the following criteria:

- a. Be involved with symptomatic breast work
- b. Have skills in clinical examination
- c. Have training in communication and 'breaking bad news', as required by the cancer peer review standards.

Symptomatic breast imaging

In order to gain and maintain expertise each radiologist involved in symptomatic breast work should fulfil the following criteria:

- 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 500 symptomatic cases per year.

In addition, each radiologist should fulfil the following criteria:

- a. Have attended an RCR approved course
- 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
- d. Comply with RCR requirements for training and continuing professional development (CPD)
- e. Have access to pathology and/or surgical follow-up data
- f. Undertake formal audit of performance.

It would be advantageous also to meet the following criteria:

- a. Be involved with breast screening
- b. Have skills in clinical examination
- c. Participate in an approved radiologists' performance quality assurance scheme for mammography
- d. Have training in communication and 'breaking bad news', as required by the cancer peer review standards.

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