

QUALITY ASSURANCE GUIDELINES FOR BREAST CANCER SCREENING RADIOLOGY

Second edition

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PREFACE

This is the second revision of the NHS Breast Screening Programme (NHSBSP) *Quality Assurance Guidelines for Breast Cancer Screening Radiology*. It updates and replaces those published in December 2005.¹ These new guidelines take into account the increasing professional participation of radiographers and breast clinicians, as well as radiologists, in the breast screening process. They also reflect the changes in performance that have been achieved in the NHSBSP over the past six years. They have been the subject of wide consultation within the relevant professional groups working in the breast screening programme, among them

- the National Co-ordinating Committee for Quality Assurance Radiologists, whose members consulted breast imaging radiologists in their regions
- the Royal College of Radiologists Breast Group
- the Association of Breast Clinicians
- the Society of Radiographers
- the United Kingdom National Co-ordinating Committee for Breast Pathology
- the Association of Breast Surgery at BASO National Screening Committee

The editors also gratefully acknowledge the contribution of Will Thompson and Karen Duncan to the quality assurance (QA) visits guidelines at Appendix 5.

1. INTRODUCTION

The principal objective of these guidelines remains the general rise in standards of performance in the NHSBSP. The guidelines take into account changes in practice and in the personnel involved, such as the widespread use of double reading and the routine involvement of radiographers and breast clinicians as screening mammography readers. These guidelines are in line with the expected further changes to the breast screening programme (namely the transition to full-field digital mammography and extension of routine invitations to women aged 47–73 in England). The professional responsibilities and standards in these guidelines apply to all screening practice administered by the NHSBSP but the achievable standards (formerly targets) apply only to routine screening of women from 50 up to their 71st birthday at invitation. Separate achievable standards and screening protocols apply to those screened because of increased risk of breast cancer.

Those involved in screen reading should, by repeated self-assessment, audit of practice and continuing education, strive to maintain and improve their skills to ensure that all women attending for mammographic screening receive an excellent service with minimal adverse effects.

The director of breast screening is responsible for ensuring that these guidelines, together with the *Clinical Guidelines for Breast Cancer Screening Assessment*,² are applied locally and incorporated into local clinical governance protocols and consultant appraisal.

1.1 Organisation of breast screening radiology quality assurance

The Royal College of Radiologists (RCR) is responsible for professional standards in radiology and also for approving training of radiologists. Standards for radiographers are prescribed and approved by the Society and College of Radiographers (SCoR).*

The Department of Health Advisory Committee on Breast Cancer Screening is responsible for considering issues relating to breast cancer screening and for making recommendations on policies for screening practice in England. The committee has representation from each of the main professional groups involved in providing the breast screening service together with representatives for Scotland, Wales and Northern Ireland, the Director of NHS Cancer Screening Programmes and representatives from the Cancer Screening Evaluation Unit. A separate advisory committee exists in Scotland.

There is a national coordinating committee for each of the professional groups involved in the NHSBSP. The remit of each of these committees is to ensure that the quality of care provided in the NHSBSP is satisfactory as measured against the national QA minimum standards³ and current professional practice and knowledge.

The NHSBSP Radiology Quality Assurance Coordinating Committee consists of representatives from each of the English regions, one representative each from Scotland, Wales and Northern Ireland and representation from the national breast screening training centres. The committee may co-opt representatives from other groups as and when appropriate. The principal remits of the Radiology Quality Assurance Coordinating Committee are to review the standards that radiologists working in screening should reasonably be expected to achieve, to examine relevant data to assess screening radiology performance and to make recommendations on changes in standards and radiological practice in the NHSBSP.

*See the RCR website at <http://www.rcr.ac.uk/> and the SCoR website at <http://www.sor.org/>.

Each regional radiology coordinator is appointed by the regional quality assurance director, has a (renewable) three-year term of office, and is formally appraised each year by the director. Coordinators are responsible for ensuring that standards are maintained in their region, for bringing appropriate local issues for debate at the national meeting, for canvassing local opinion on national radiological initiatives and for feeding back locally on issues discussed and decided in the national forum.

2. QUALITY STANDARDS

2.1 Introduction

The quality standards in this document are those of the NHSBSP and refer primarily to monitoring at unit level. They are divided into three separate tables and relate to women from 50 up to their 71st birthday called or recalled for screening as part of the NHSBSP. Standards will be amended to apply to the age range 47–73 if this extension to the programme progresses beyond the trial stage.

Each table has four columns

Objective

These are the aims of the NHSBSP in relation to specific quality issues.

Criteria

These are the parameters by which the achievement (or not) of the objective will be measured.

Minimum standard

These figures represent the levels of performance that are the minimum acceptable for any breast screening unit. Where the minimum standard is shown as 'greater than' or 'equal to', any level of performance below that standard should be investigated by the QA team. Similarly, where the minimum standard is shown as 'less than' or 'equal to', any level of performance above that standard should be investigated by the QA team.

Achievable standards

If the programme is to achieve a reduction in mortality similar to that in the Swedish two-county trial,⁴ over 50% of UK units have to achieve the target invasive cancer detection rate (objective 1) and minimum standards for attendance (objective 6) and round length (objective 7). All units should aim to achieve these three key standards, which define the quantity of the mortality reduction. The other achievable standards relate to the quality of the screening process and should be achievable individually by one-third of units within the NHSBSP.

The data from which to measure a unit's performance are all derived from national and local statistical returns. It is important to remember that normal variation can play a significant part in performance, particularly when looking at small numbers. Monitoring should therefore be undertaken with care and in many circumstances aggregated over a number of years. A team's results can be used by individuals as evidence to support appraisal and revalidation.

The performance of individual team members can be lost within a unit's global results, and this may mask individual underperformance. Screening and assessment are a team process but individuals are responsible for their own training: they should ensure that they are trained for the tasks they carry out and undertake appropriate training for any new tasks or techniques. Individuals should assess their performance against peers within their unit and region, eg cancer detection rates, missed cancer detection rates, recall rates, and the positive predictive value (PPV) of referral rates. It is the responsibility of all medical and non-medical practitioners providing radiology services to monitor their team's and their own performance and report any problems through their Trust's clinical governance process.

2.2 Core radiological quality standards

The standards shown in Table 1 relate to cancer detection. Achieving them is fundamental to the NHSBSP's aim to reduce mortality.³

Table 1 Core radiological quality standards

Objective	Criteria	Minimum standard	Achievable standard
1. To maximise the number of cancers detected	(a) The rate of invasive cancers in eligible women invited and screened	Prevalent screen ≥3.6 per 1000 <i>Incident screen</i> ≥4.1 per 1000	Prevalent screen ≥5.1 per 1000 <i>Incident screen</i> ≥5.7 per 1000
	(b) The rate of cancers detected that are in situ carcinoma	Prevalent screen ≥0.5 per 1000 <i>Incident screen</i> ≥0.6 per 1000	
	(c) Standardised detection ratio (SDR) for invasive cancers	≥ 1.0	≥ 1.4
2. To maximise the number of small invasive cancers detected	The rate of invasive cancers < 15 mm in diameter detected in eligible women invited and screened	Prevalent screen ≥2.0 per 1000 <i>Incident screen</i> ≥2.3 per 1000	Prevalent screen ≥2.8 per 1000 <i>Incident screen</i> ≥3.1 per 1000

2.2.1 Cancer detection rates

Invasive cancers (objectives 1a, 1c)†

The criterion used to measure whether the number of cancers detected is being maximised is the rate of invasive cancers detected in eligible women from 50 up to their 71st birthday who are both invited and screened every three years. Microinvasive disease is excluded. There is a geographical variation in the incidence of breast cancer, with reduced incidence in the north compared with the south; however no significant pattern has emerged that would allow different standards to be set for different parts of the country.

The age of women screened is the major determinant of cancer detection rates. This is corrected for by means of an SDR, which allows confidence intervals to be measured and performance over a longer period (usually three years) to be easily calculated (see Appendix 1). The SDR for any given screening programme is the ratio of the observed number of cancers to the expected number. Expected numbers of invasive cancers detected for individual screening programmes can be predicted by knowing the numbers and age profiles of those attending and applying them to the age-specific expected detection rates. The standard for each screening service is an SDR of 1.4 for any given year, with a minimum standard of 1.0. These standards apply to all screening units, regardless of size. If a unit's performance falls below the minimum level, data for the last three years should be examined. An investigation to establish the reasons for this apparently poor performance may be undertaken at the discretion of the QA team. SDR values for short periods of time should always be considered in the context of long-term performance.

†Standards 1a and 1c are for invasive cancers only and exclude in situ carcinoma and in situ carcinoma with microinvasion. The minimum standards for in situ and microinvasive disease detection are in addition to these numbers.

The minimum standard of ≥ 1.0 has been set to allow for statistical variation in the detection rate. All screening services regardless of size are thus expected to achieve the stated minimum standard. The fact that a target population is smaller than the recommended size does not justify failure to do so. Services smaller than the recommended size (9000 invited women screened per annum) can be justified only where they adhere to national minimum standards.⁵

The prevalent detection rate assumes that most women attending for a prevalent screen are between the ages of 50 and 52.9 years (average 51.5 years), when the underlying incidence of breast cancer is estimated to be 17.3 per 10000 and the predicted number of cancers detected in women attending for their first screen is 2.1 times the underlying incidence at age 51.5 years. (This factor is derived from the cancer detection rate achieved in the Swedish two-county study.⁴)

The incident detection rate assumes that the majority of women attending for an incident screen will be between the ages of 53 and 69.9 years (average 61.5 years). It is assumed that screening will detect 62% of cancers expected to occur over a three-year period (based on the performance of the Swedish two-county study⁴).

Ductal carcinoma in situ (objective 1b)

The number of in situ carcinomas expected includes ductal carcinoma in situ (DCIS), lobular carcinoma in situ and microinvasive disease. Detection of DCIS at screening, particularly high-grade types, is assumed to be a factor contributing to long-term reduction in mortality although no firm scientific evidence currently exists to confirm this. The majority of DCIS detected at screening is of the high-risk type. It is believed to be good practice to detect and treat DCIS and for this reason the minimum standard is set at ≥ 0.5 per 1000 for prevalent screens and ≥ 0.6 per 1000 for incident screens. **DCIS numbers include in situ carcinoma and in situ carcinoma with possible or definite microinvasion.** This is based on 10% of the total target cancer detection rate. No achievable standard or upper limit has been set because there is evidence that high DCIS detection rates are associated with high SDR.⁶

2.2.2 Tumour size

It should be the aim of any breast screening programme to detect small breast cancers. The standard for invasive tumours less than 15 mm in diameter has been included as the primary measure as there is good scientific evidence that this size represents the prognostic threshold.⁷ For any individual screening service the number of tumours detected that are less than 15 mm in diameter will give a more reliable measure of performance (as confidence limits will be smaller than for the number of tumours of 10 mm or less). The expected standard is that 55% of the screen-detected invasive cancers will be less than 15 mm in maximum diameter for both prevalent and incident screens. This is based on analyses of the results of the Swedish two-county study.⁴ The minimum standard is 0.85 of the expected standard.

Histological size of invasive carcinoma (fixed specimen) is used where available. Where no histology is available, the best available size from mammography, ultrasound or clinical examination should be used. Note that cases of DCIS with possible or definite microinvasion are included with DCIS, rather than with invasive cancers. There is concern that histological size may not be accurately recorded when size is recorded as 'less than' as opposed to 'less than or equal to' and pathologists should be discouraged from 'rounding up' histological size measurements.

As well as being related to tumour size, the prognosis of invasive breast cancer is correlated with a number of other factors. Those that should be routinely available include histological lymph node status, histological tumour grade and tumour type. Small size, lymph node negative disease, low histological grade and tumour special type are all associated with better prognosis. Screening units are encouraged to collect information on the success or otherwise of mammography readers and those carrying out assessment clinics in detecting tumours with these characteristics.

Screening units should collect details of the histopathology of all screen-detected cancers on an annual basis. For invasive carcinoma this should include tumour size, lymph node status and histological grade; for in situ carcinoma, it should include tumour size, type and grade.⁸

2.3 General radiological quality standards

Table 2 General radiological quality standards

Objective	Criteria	Minimum standard	Achievable standard
3. To minimise the number of women screened who are referred for further tests [‡]	(a) The percentage of women who are referred for assessment	(a) Prevalent screen < 10% <i>Incident screen < 7%²</i>	(a) Prevalent screen < 7% <i>Incident screen < 5%²</i>
	(b) The percentage of women screened who are placed on early recall	(b) < 0.25%	(b) ≤ 0.12%
4. To ensure that the majority of cancers, both palpable and impalpable, receive a non-operative tissue diagnosis of cancer	(a) The percentage of women who have a non-operative diagnosis of invasive cancer by needle histology after a maximum of two attempts	(a) ≥ 90%	(a) ≥ 95%
	(b) The percentage of women who have a non-operative diagnosis of DCIS by needle histology after a maximum of two attempts	(b) > 85%	(b) > 90%
5. To minimise the number of unnecessary operative procedures	The rate of benign biopsies	Prevalent screen < 1.5 per 1000 <i>Incident screen < 1.0 per 1000</i>	Prevalent screen < 1.0 per 1000 <i>Incident screen < 0.75 per 1000</i>

[‡]Further tests' includes all second appointments where procedures (including further views and/or clinical examination) beyond those normally undertaken at first appointment are carried out.

2.3.1 Screen reading specificity (objective 3)

As shown in Table 2, the minimum standard for the recall of women for further assessment is less than 10% of women screened (achievable standard less than 7%) for their prevalent screen. For subsequent screens it is less than 7% (achievable standard less than 5%). Where particularly high cancer detection rates are found it may not be possible to reduce referral for assessment rates greatly. These standards relate to women from 50 up to their 71st birthday called or recalled for screening as part of the NHSBSP. This is a measure of radiological screen reading specificity and it excludes technical recalls. All readers are expected to attain the minimum standard of <10% recall. High recall rates result in unnecessary anxiety for women screened and create an avoidable burden on the screening assessment process. Quality Assurance Reference Centres (QARCs) should thoroughly investigate all screening services that have recall rates above the minimum standard. All services with prevalent and/or incident recall rates higher than the minimum standard must carry out arbitration of all prevalent and/or incident recalls as a matter of routine.

Wherever possible mammography screen readers should also be involved in breast screening assessment as part of a multidisciplinary assessment team (MDT) that employs the triple approach to diagnosis. This will ensure that film readers experience at first hand the outcome of their screening recalls. The assessment process is enhanced when it includes pre-treatment clinical management meetings that provide each member of the team with information on his or her diagnostic accuracy. As a minimum all film readers should formally audit their film reading performance and compare their results with those of their peers. If their individual recall rates when acting as first reader are satisfactory, readers should review all the cases they did not recall where women were subsequently proven to have cancer. If their recall rates are too high, readers should also review all their false positive recalls.

To achieve a significant reduction in breast cancer mortality it is of prime importance that small (< 15 mm diameter) invasive breast cancers are detected. Where breast cancer detection rates are lower than predicted and the quality of service is satisfactory less emphasis should be placed on achieving low recall rates. Recall rates of less than 2% for prevalent attendees are more likely to be associated with low small-cancer detection rates.

Positive predictive value for recall (particularly when used in a PPV recall diagram) is a powerful audit tool for demonstrating the relationships between sensitivity and specificity and can be used to suggest ways of improving performance.

2.3.2 Short-term recall (objective 3b)

This standard applies to women recalled for screening assessment at an interval shorter than the normal screening interval (currently three years) after a previous screen and attendance for assessment. It is not acceptable practice to place a woman on short-term recall without first explaining the reason(s) for this to her in person and offering appropriate counselling. This means that all women on short-term recall should have previously attended for assessment. Short-term recall should not be used as a routine outcome following assessment. Every effort should be made to obtain a definitive diagnosis at initial assessment and short-term recall should be used only in exceptional circumstances and with fully informed consent, as it is associated with significant anxiety.⁹ No more than one short-term recall outcome should be used per woman per normal (three year) screening cycle. Women on short-term recall should be returned to an assessment clinic, where they can be informed without delay of the results of any further imaging or other investigations. They should not be returned to a routine screening session, where further management cannot usually be discussed directly with them. Short-term recall at an interval of less

than one year should be exceptional, as it is unlikely to assist the diagnostic process.

2.3.3 Non-operative diagnosis (objective 4)

A non-operative diagnosis of malignancy is highly desirable as it allows informed pre-treatment counselling of the patient and facilitates one-stage treatment. The minimum standard is that at least 90% of invasive cancers should be diagnosed non-operatively. The achievable standard is 95%. The equivalent standards for DCIS are 85% and 90% respectively. Only definitive diagnoses of malignancy (B5) should be included; open surgical biopsy is not included.

Repeated attendances for assessment or needle biopsy during a single screening episode are likely to be associated with unnecessary anxiety. A definitive diagnosis should be achieved in the minimum number of assessment visits and women should not have to make more than two visits for interventional procedures. Core biopsy is the expected standard for biopsy procedures and vacuum-assisted biopsy should be considered if diagnostic difficulty is anticipated.

Standards for non-operative diagnosis adequacy and miss rates are defined in *Guidelines for Non-operative Diagnostic Procedures and Reporting in Breast Cancer Screening*.¹⁰ These standards are summarised in Table 3.

Table 3 Non-operative diagnostic procedures

Objective	Criteria	Minimum standard	Achievable standard
6. Minimise the miss rate for core biopsy of invasive breast cancer	Negative core biopsy (B1 + B2) from invasive cancer at the first attempt	<5%	<1%

2.3.4 Benign biopsies (objective 5)

Surgical open biopsies are carried out specifically to establish a diagnosis.¹¹ The definition excludes needle biopsy and diagnostic vacuum-assisted mammotomy. Therapeutic excision biopsy of known benign lesions undertaken at the request of the woman or her surgeon are also excluded. In order to minimise unnecessary surgery, the number of open surgical biopsies performed as a result of screening that prove to be benign should be as small as possible.¹¹ Wherever possible a definitive diagnosis should be obtained by non-operative techniques, thereby avoiding the need for surgical excision. However benign biopsy may be unavoidable where imaging, clinical or cytological/histological features or the woman's choice mean that formal surgical excision is needed to obtain a definitive diagnosis.

2.4 Quality standards for screen reading

Table 4 Service quality standards

Objective	Criteria	Minimum standard	Achievable standard
7. To minimise anxiety for women who are awaiting the results of screening	The percentage of women who are sent their result within two weeks	≥90%	100%
8. To minimise the interval from the screening mammogram to assessment	The percentage of women who attend an assessment centre within three weeks of attendance for the screening mammogram	≥90%	100%
9. To minimise diagnostic delay for women who are diagnosed non-operatively	Proportion of women for whom the time interval between non-operative biopsy and result is one week or less	≥90%	100%

2.4.1 Timely processes (objectives 7–9)

Screening can be stressful for women and it is appropriate that all stages of the process are undertaken in a timely fashion, in accordance with the standards set out in Table 4.

Having cytology or core biopsy causes particular anxiety and a quality service would be expected to inform women of the results of these procedures without significant delay. Ideally women should be informed of any results in person; where results are given by telephone, they should be confirmed in writing.

3. STANDARDS FOR WORKING PRACTICE

3.1 Introduction

The tasks of reading screening mammograms and assessing screen-detected abnormalities, including ultrasound and needle biopsy, have traditionally been performed by radiologists. However the increasing demand for manpower as a result of the expansions of the NHSBSP has resulted in the development of 'skill mix' and, as a result, many of these tasks are now shared with appropriately trained breast physicians, advanced practice radiographers and consultant radiographers. These breast screening radiology guidelines are written to reflect the changes introduced by the adoption of skill mix and the need to focus on standards for tasks and responsibilities rather than job titles. The tasks in question are:

Screening

Interpretation of screening mammograms

Assessment

Clinical history and examination

Interpretation of appropriately requested additional mammographic views

Ultrasound of the breast and/or 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.

An assessment clinic must be directed and led by a consultant radiologist, breast physician or consultant radiographer proficient in screen reading and all of the assessment tasks prescribed in the *Clinical Guidelines for Breast Cancer Screening Assessment*, 2010.² Radiologists, breast physicians and advanced radiographic practitioners working in the NHSBSP may be proficient in only some of these tasks, in which case they may participate in screening assessment but should not lead the assessment process. The expectation is that newly appointed breast radiologists will have satisfied RCR training requirements and be proficient in all tasks.

3.2 Responsibilities common to all staff

All staff involved in the interpretation of mammograms or participating in assessment are responsible for

- a) ensuring that they acquire and maintain a comprehensive knowledge of breast disease and the necessary skills. This will involve: attendance at an approved breast screening training course; regular reading of relevant articles and journals; attendance at scientific meetings that include breast imaging. Details of the initial training course will vary with the professional group
- b) participating actively in and encouraging the understanding of breast screening as a multi-disciplinary team activity. This will involve liaising routinely and regularly with other radiology/radiography staff, pathologists, cytologists, breast physicians, surgeons, breast care nurses and

physicists. It may also involve clinical and medical oncologists, geneticists, plastic surgeons, consultants in public health medicine, QARCs and cancer registry staff

- c) encouraging and participating actively in formal audit of the performance of the unit and individuals. This will require staff to agree to the audit of their own work and comparison with their peers and to demonstrate a willingness to alter their practice where indicated by the outcomes.

3.3 Working practices common to all staff

To achieve the quality standards professionals should

- a) attend multidisciplinary clinical management meetings
- b) comply with the requirements for training and continuing medical education (CME)/continuing professional development (CPD) as prescribed by the appropriate Royal College or Society
- c) have access to pathology and/or surgical follow-up data.

It is also recommended that a screening radiologist be

- d) employed for a minimum of three programmed activities dedicated to direct clinical care in breast imaging (both screening and symptomatic)
- e) normally involved and skilled in all aspects of breast screening, including mammography reading, screening assessment, and MDT meetings at which screening cases are discussed.

Professional standards for screening and symptomatic breast imaging prepared by the RCR Breast Group are set out in *Guidance on Screening and Symptomatic Breast Imaging*.¹²

3.4 Screening mammography reader responsibilities

In addition to the activities listed above, it is the responsibility of a mammography reader involved in breast screening to

- a) participate in the formal audit of mammography reading performance. This will require mammogram readers to compare their performance with their peers' and to demonstrate a willingness to alter their practice if indicated by the outcomes. In a few cases these may suggest that retraining is required, eg by secondment to an RCR-accredited training centre. This audit should include the regular review of NHSBSP objectives, which are to
 - maximise the number of carcinomas detected in the screened population
 - maximise the number of small carcinomas detected
 - minimise the number of women recalled for assessment
 - minimise the number of interval cancers, particularly false negative cases, and encourage surgeons to request mammography when a carcinoma is detected so as to minimise the number of unclassifiable cases
- b) adhere to local 'right result' procedures so that the result of the screen reading is recorded accurately and conveyed to the woman in a timely manner (within two weeks of screening attendance)
- c) in the case of radiologists and other professionals involved in reading screening mammograms, ideally be associated with the local symptomatic breast imaging service and involved in the imaging of patients with symptomatic breast problems. As well as maintaining and developing

- clinical skills, this represents the best use of expertise and will help to ensure that quality standards for symptomatic services are comparable with those of the NHSBSP
- d) undertake a minimum of 5000 screening and/or symptomatic cases per year
 - e) participate in PERFORMS (Personal Performance in Mammographic Screening) or a similar approved radiology performance QA scheme for mammography
 - f) in the case of mammography readers, wherever possible participate in screening assessment and MDTs. If this is not achievable, monthly audit of screening mammography outcomes (recall rate and assessment outcome by abnormality type) must be carried out.

3.5 Facilities and protocols for mammography reading

3.5.1 Facilities and environment

Mammography readers should ensure that facilities for screen reading are suitable for their purpose. For film–screen mammography, equipment should include adequate access to a film multiviewer, and a magnifying glass (or other magnifying device) should be used routinely when viewing screening mammograms. For digital mammography, appropriate high-resolution dedicated mammography review workstations must be provided. Mammography reading facilities must be sited in an environment suitable for uninterrupted screen reading with appropriate lighting.

3.5.2 Double reading of mammograms

Double reading of mammograms by two film readers is recommended and should be considered mandatory in units that have moved entirely to digital mammography. Inexperienced readers should be paired with experienced readers and, ideally, readers with high recall rates should be paired with readers who have below-average recall rates and low cancer miss rates.

3.5.3 Previous mammograms

Previous mammograms should be available to readers at the time of screen reading. For film–screen mammography incident examinations the previous and/or at least penultimate screening mammograms should be available for review. It is the responsibility of the film reader to decide whether it is necessary to obtain previous mammograms held at another unit. If previous film–screen mammograms are needed the originals, rather than copy films, should be obtained whenever possible.

Within the NHS no charge should be made for the transfer of patient information from one unit to another and NHSBSP units should provide the original mammograms. A reasonable fee may be applied for the transfer of films outside the NHS, to cover administration and carriage. Radiologists should establish reciprocal links between the NHSBSP and the private sector to encourage the free flow of relevant radiological data and ensure that patient care is not compromised.

3.5.4 Signs and symptoms

A system should also be in place to alert the reader at the time of screen reading to relevant clinical signs or symptoms noted by the radiographer or reported by the woman while attending for screening (see *Information and Advice for Health Professionals in Breast Screening*).¹³ It is the

responsibility of the reader to assess the significance of these breast symptoms or signs and ensure that appropriate further assessment of the woman takes place. There should be a written protocol that prescribes local practice for signs and/or symptoms detected through screening.

3.6 Staff directing an assessment clinic

In addition to the activities listed above, it is the responsibility of the consultant radiologist, breast physician or consultant radiographer directing an assessment clinic to

- a) ensure that they acquire and maintain a comprehensive knowledge of breast disease and the necessary skills to conduct the full diagnostic process, as described in the NHSBSP *Clinical Guidelines for Breast Cancer Screening Assessment* (2010).² These include
 - all assessment tasks listed above
 - training in communication and 'breaking bad news', as required by the cancer peer review standards.

This will involve attendance at RCR-approved breast screening training courses, regular reading of appropriate articles and journals, and attendance at scientific meetings that include breast imaging. Details of the RCR Breast Group curriculum for sub-specialty training in breast imaging appear at Appendix 2. The professional responsible for directing the assessment clinic is expected to participate in CME and ensure continuing accreditation by his or her relevant college, society or other professional academic accreditation body. (Recommendations for CME appear in Appendix 3, while NHSBSP national training centres are listed in Appendix 4.)

- b) oversee and give advice on radiographic work and standards.

4. INTERVAL CANCERS

4.1 Interval cancer data

Interval cancers are defined as breast cancers diagnosed in the interval between scheduled screening episodes in women who have been screened and issued with a normal screening result. Such cancers are inevitable in any screening programme but their numbers should be kept to a minimum. A high proportion of interval cancers will reduce the likelihood of reducing mortality in the population to whom screening is offered. Analysis of interval cancer data should take place on a regional basis, as the number of interval cancers occurring in individual screening units each year is relatively small and analysis of them is likely to be meaningful only when several years' data are available. Individual screening units should nevertheless continue actively to participate in the collection and collation of interval cancer data. These should be examined alongside other screening data (such as invasive cancer detection rates and SDRs) when considering the performance of a breast screening programme.

Auditing the proportions of interval and screen-detected breast cancers and classifying their types (see section 4.3.2) will help in the evaluation of the NHSBSP and its achievements in the longer term. These data enable estimates to be made of overall programme sensitivity, for example, and may highlight areas meriting further attention.

Expected interval cancer rates for the target screening age group from 50 up their 71st birthday are shown in Table 5.

Table 5 Expected interval cancer rates

	0–24 months	25–36 months
Number of invasive cancers per 1000 women screened	1.2	1.4

4.2 Review of interval cancers

4.2.1 Principles

Radiological review and the classification of interval cancers in a breast cancer screening programme are particularly valuable for their educational benefit to film–screen readers. By viewing cases where the mammograms show very subtle changes in malignancy, film readers have been able to improve their skills in detecting small breast cancers. The review protocol recognises the need for consistency and objectivity in the review process (see Figure 1). As the review and classification process involves opinions on cases from individual film readers, however, it is unlikely that any process would yield entirely consistent results among all programmes and regions.

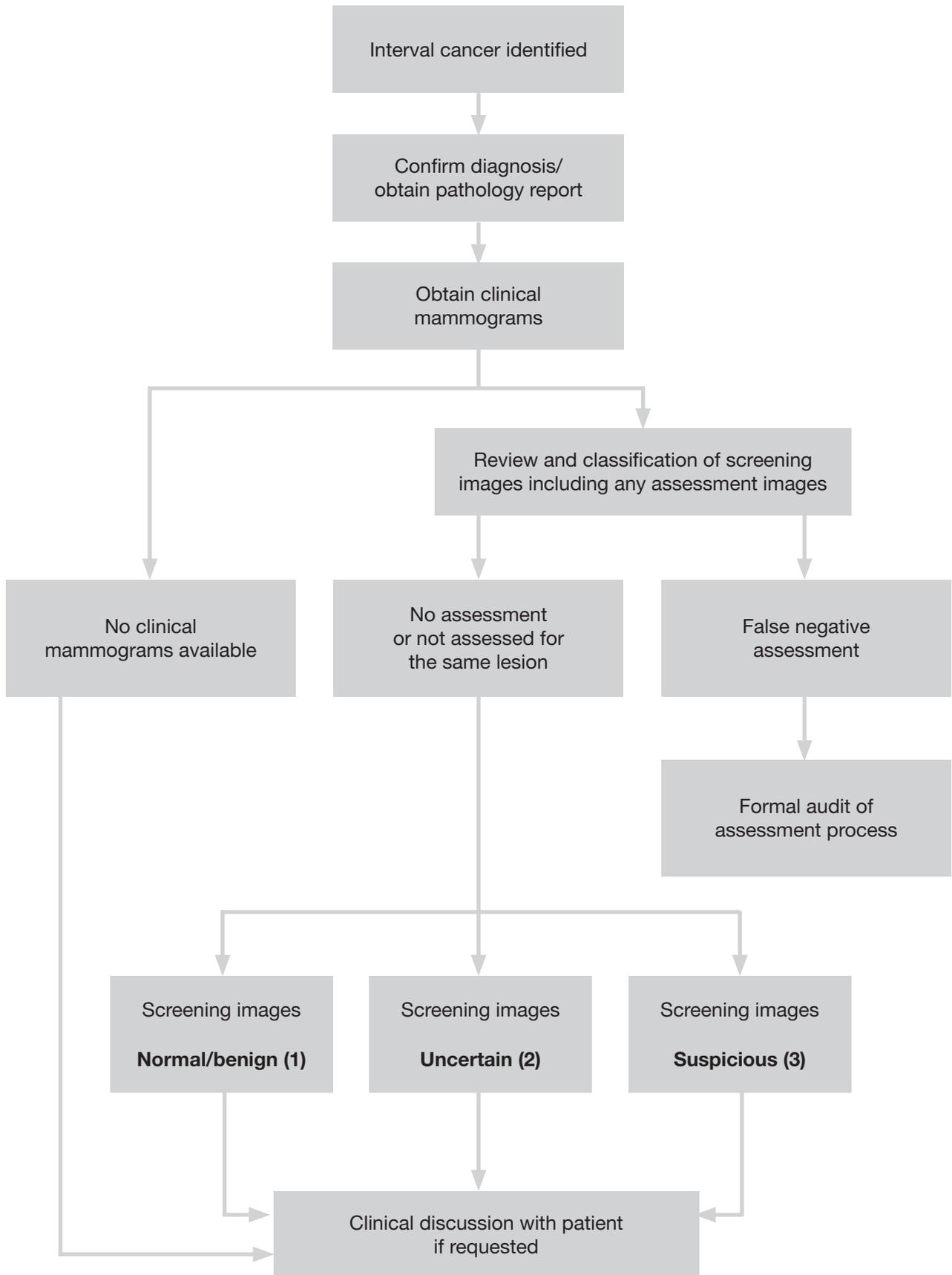


Figure 1 Interval cancers: review of screening mammograms.

4.2.2 *Aims of review*

The aims of the review protocol are to

- a) ensure that a standard process exists for the review of previous mammograms and that radiologists and film readers continue to learn from interval cancer film review
- b) provide helpful and understandable information to women diagnosed with breast cancer who request the results of the audit of their previous films.

4.3 **Information flow**

4.3.1 *Identifying interval cancers*

Interval breast cancer cases may be identified from a number of sources. These include symptomatic breast clinics, pathology laboratories and eventually the cancer registry. When a breast cancer case is identified in a woman in the screening age range in a hospital with a breast screening unit, the clinician treating the woman should ensure that the Director of Breast Screening is informed. He or she is then responsible for informing the regional QARC. Where the hospital treating the woman for her breast cancer does not have a screening unit, the clinician treating her should inform the QARC directly. Patients with interval breast cancers may also be identified through liaison between the QARC and the local cancer registry. Identifying details to be passed to the screening unit or QARC might include

- name
- date of birth
- address
- GP/practice details
- NHS number.

4.3.2 *Quality assurance reference centre actions*

Once the QARC has received the identifying details of a patient diagnosed with breast cancer, they should check her NHSBSP history and confirm the identification of interval cancers. They should then assign the case to one of the following categories

- interval cancer (is between screens)
- cancer in a non-attender (has never accepted invitation)
- cancer in a 'lapsed attender' (more than three years elapsed since last screen and since reinvited, or over invitation age)
- cancer in an uninvited woman (has never been invited).

The QARC should inform the relevant screening unit of breast cancers that are interval cases and therefore require radiological review. The screening unit should also be given details of the woman's diagnosis and her treating clinician.

On receiving these details the breast screening unit should request the symptomatic mammograms and undertake a radiological review to classify the case (as described in section 4.4).

Once the case has been reviewed, the breast screening unit should inform the QARC. The unit that screened the woman should then retain the named patient data in order to discuss the review's findings with her at a later date if she requests it.

4.4 Review process

The review process will be carried out at local level in the screening programme and should involve a minimum of two readers. For screening programmes with one film reader, a film reader from another programme should be invited to participate in the review. If the two film readers cannot agree on the classification of a case, a third will be asked to arbitrate. Some regions or programmes may choose to undertake a further review process, involving more than two readers, for educational purposes.

The previous screening mammograms should initially be reviewed by each reader independently and without sight of the mammograms taken at diagnosis (if these are available). It is not necessary to mix normal cases with the screening films being reviewed. The presence of any abnormal mammographic sign or feature should be recorded and the radiology level of suspicion for malignancy indicated using the three-point classification described in section 4.5. Once this is done, the diagnostic films should be reviewed to confirm that any subtle or suspicious signs detected on the screening films match the site of the confirmed breast cancer on the diagnostic films.

4.4.1 False negative assessment

Women should be the subject of specific formal audit if they have previously been assessed and either present with breast cancer in the interval between screens or are diagnosed at the subsequent screen. The first task is to establish whether the woman was assessed initially for an abnormality that later proved to be the breast cancer. If so, the previous assessment process must be reviewed in detail to verify whether or not the assessment processes then in place were followed. All cases of false negative assessment must be reported to the local QARC within three months of ascertainment. The reason the cancer was not detected at previous assessment must be clearly indicated on the Proforma for False Negative Assessment, which will be published separately on the NHSBSP intranet site.

4.4.2 Quality assurance review

Interval cancer films and the results of the interval cancer review will be analysed by the Regional QA Radiologist during a QA visit, to ensure that the review process is being fully adhered to. (For information on QA visits see Appendix 5.)

4.5 Classification of previous screening mammograms

Category 1: Normal/benign

Normal or benign mammographic features.

Category 2: Uncertain

A feature is seen with hindsight on the screening mammogram that is difficult to perceive or that does not have clearly benign or clearly malignant features. All film–screen readers may have difficulty perceiving or interpreting such subtle mammographic appearances, eg asymmetric soft tissue density or parenchymal distortion.

Category 3: Suspicious features

An abnormality is seen on the mammogram which has features suggesting malignancy, eg pleomorphic microcalcification or spiculate mass.

The relevant QARC must be informed of these categories of interval cancer by case annually.

False negative assessment cases must be reported within three months using the appropriate proforma (see section 4.4.1).

4.6 Disclosure of audit results

Detailed guidance on the psychological and medico-legal aspects of the audit of interval cancers and the disclosure of audit results can be found in the NHS Cancer Screening Programmes' publication *Disclosure of Audit Results in Cancer Screening: Advice on Best Practice*.¹⁴

4.7 Entry of interval cancers on National Breast Screening System

All interval cancer cases should be entered on the National Breast Screening System (NBSS).

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APPENDIX 1: CONFIDENCE INTERVALS

All NHSBSP staff with a QA role must be able to assess performance and interpret performance data accurately. Understanding ‘confidence intervals’ (or ‘confidence limits’) is a crucial part of that process. This appendix offers an explanation of the confidence interval, what it means and how it is calculated. It begins with a general introduction adapted in part from material on the NHS Choices website (<http://www.nhs.uk/news/Pages/Newsglossary.aspx#Confidenceinterval>). This is followed by ‘Confidence limits for proportions’ (written by Dr Roger Blanks), which provides a more detailed explanation with worked examples.

Introduction

All estimates involve a measure of uncertainty, because studies are conducted on samples and not on entire populations. A confidence interval is a way of expressing the precision of an estimate (or the uncertainty surrounding it) and is often presented alongside the results of a study.

In the Swedish two-county trial,⁴ for example, screening significantly reduced the rate of deaths resulting from breast cancer. Women in the screening group had a 38% reduced risk of dying from breast cancer compared with those in the non-screened group. In the trial this was expressed as: ‘relative risk[§] 0.62, 95% confidence interval [CI] 0.51 to 0.75’.

The most common interval (the 95% confidence interval) shows where we confidently expect the true result from a population to lie 95% of the time: in the Swedish two-county trial, the relative risk is expected to lie between 0.51 and 0.75. The narrower the interval or range, the more precise the estimate. A confidence interval of 95% certainty is usually considered high enough for researchers to draw conclusions that are sufficiently robust to be extended from the sample to the population as a whole.

In QA we assume that a sample (or observed) cancer detection rate based on a year’s data is an estimate of a radiologist’s true annual cancer detection rate. But the accuracy of that estimate depends on its denominator, ie on the number of women screened. If only a few hundred women are screened and the denominator is small, the cancer detection rate would owe a lot to chance: if many tens of thousands are screened then the denominator would be much larger and the role of chance would shrink.

We can use confidence limits to examine the role of chance in a particular estimate. For example, a radiologist obtains a cancer detection rate of 2 per 1000, based on 20 cancers detected from 10 000 women. This is a reasonably large denominator and enables us to say with 80% certainty that the detection rate will lie between 1.4 and 2.6 per 1000. (For details of how this confidence interval is calculated, see below.) If the target rate is 4 per 1000 then we have sound evidence that this radiologist has a low cancer detection rate. On this basis we could infer that future detection rates might also be low, which would justify looking in more detail at the radiologist’s performance. But if the rate of 2 per 1000 were based on a much smaller denominator, say 1 cancer detected from 500 women screened, then its interpretation would be very different. The 80% confidence limits would in this case be 0 to 4.6 per 1000; in other words, the true cancer detection rate could exceed

[§]‘Relative risk’ compares a risk in two different groups of people. All sorts of groups are compared with others in medical research to see if belonging to a particular group increases or decreases the risk of developing certain diseases. This measure of risk is often expressed as a percentage increase or decrease, for example ‘a 20% increase in risk’ of treatment A compared with treatment B. If the relative risk is 300%, it may also be expressed as ‘a three-fold increase’.

the programme's target of 4 per 1000, making detailed scrutiny of the radiologist's performance unjustified. In both cases, the confidence limits are used to indicate the range in which we are 80% sure that the true cancer detection rate of the radiologist lies.

Confidence limits for proportions

Cancer detection rates, recall rates and the positive predictive value (PPV) can all be thought of as proportions, though they are not described in that way. By using the normal approximation to the binomial distribution we can calculate a simple confidence limit that will enable us to determine if these rates and PPV are based on sufficient numbers to provide a reasonable estimation of performance. We can calculate either the 95% confidence limit routinely used for trials and other studies or a less stringent 80% confidence limit, which is arguably more useful for proactive QA. The formulae are as follows

$$95\% \text{ confidence limit: } p \pm 1.96 \sqrt{\frac{p(1-p)}{n}}$$

$$80\% \text{ confidence limit: } p \pm 1.28 \sqrt{\frac{p(1-p)}{n}}$$

Example: Consider a reader who reads films from 3000 women, of whom 180 are recalled and 30 have cancers detected. The cancer detection rate is 10 per 1000 or 0.01 as a proportion. The recall rate is 6% or 0.06 as a proportion and the PPV is 16.7% or 0.167 as a proportion.

The 95% confidence limits around the cancer detection rate as a proportion are

$$\begin{aligned} &= 0.01 \pm 1.96 \sqrt{\frac{0.01(1-0.01)}{3000}} \\ &= 0.01 \pm (1.96 * 0.00182) \\ &= 0.01 \pm 0.00357 \\ &= 0.00643 \text{ to } 0.01357 \end{aligned}$$

Or multiplying by 1000 to report this as a rate per 1000, the cancer detection rate is 10 per 1000 (95% CI 6.43 to 13.57 per 1000). Similarly, using the above equation, the 80% confidence limit is $0.01 \pm 0.00233 = 0.00767$ to 0.01233 , or multiplying by 1000 is 10 per 1000 (80% CI 7.67 to 12.33 per 1000).

We can interpret the 95% confidence interval as suggesting a 19 in 20 chance that the true value is between 6.43 per 1000 and 13.57 per 1000, while the 80% confidence interval suggests a 4 in 5 chance that the true value is between 7.67 per 1000 and 12.33 per 1000. In both cases the best estimate is 10 per 1000 and we can argue that this is a reasonable estimate.

What if the reader read 300 films, referred 27 women and detected three cancers? The cancer detection rate is still 10 per 1000, but the 80% confidence limits are 2.65 per 1000 to 17.35 per 1000. There is thus a 4 in 5 chance that the true cancer detection rate, after allowing for chance, is between 2.65 per 1000 and 17.35 per 1000. Of course, the 95% confidence limits are even wider and less precise; we can conclude that there is a 19 in 20 chance that the true value is between

-1.3 per 1000 and 21.3 per 1000. The negative value occurs because the formula is not very good when the overall numbers involved in the study (n) become very small. A negative number of cancers detected is impossible, however, so any negative values are interpreted as a zero detection rate. This means that we are 95% sure that the true value is between 0 and 21 per 1000 – a range so large that it effectively tells us nothing at all about the reader's cancer detection rate because the numbers are so small that they relate more to chance than performance. So we can conclude that when small sample sizes (in this case only 300 women) are screened the cancer detection rate is not a useful measure.

But what about the recall rate? Based on 27 women referred, the recall rate is 9%. Converting this to proportions and using the above formulae again we can calculate the 80% confidence limits as 7% to 11%. The recall rate is thus a more useful measure, even when based on relatively small numbers of women screened.

The formulae given above are most accurate with larger numbers and least accurate when the numbers are very small. When small numbers of women are screened and wide confidence limits are encountered we can conclude that the measurement is not useful. This demonstrates the clear advantage of reporting the confidence intervals in order to indicate not only the accuracy of the measure (the more narrow the confidence interval, the more accurate the measure) but also whether the measurement is useful. As noted, the 80% confidence limit may be more useful for proactive QA, even though the 95% limits are the most commonly used in scientific studies.

APPENDIX 2: SUB-SPECIALTY TRAINING – BREAST IMAGING

For current details of The Royal College of Radiologists' *Specialty Training Curriculum for Clinical Radiology* see <http://www.rcr.ac.uk/RCRcurriculum/2010>.

APPENDIX 3: CONTINUING MEDICAL EDUCATION

Radiologists working in breast screening should ensure that their knowledge and skills are up to date. This should include

- participation in PERFORMS or an equivalent assessment of film interpretation
- at least 25% of category 1 CME points should be in breast radiology
- participation in audit and interval cancer review
- development of new skills to address new technology challenges, eg vacuum-assisted biopsy, magnetic resonance imaging (MRI) and MRI-guided biopsy.

The national training centres have a continuing role in

- training new entrants into the specialty
- organising refresher courses
- providing individual tuition for radiologists with a specific problem
- reacting to the training needs identified by the various professional QA groups.

The contact addresses of the NHSBSP training centres are provided in Appendix 4.

All training centre activities that are relevant to breast screening radiology should be registered for CME points or equivalent.

APPENDIX 4: NHSBSP TRAINING CENTRES

Nottingham Breast Screening Training Unit
City Hospital Campus
Nottingham University Hospitals
Hucknall Road
Nottingham
NG5 1PB

Tel: 0115 969 1689

Breast Screening Training Unit
Nightingale Centre
Withington Hospital
Manchester
M20 0PT

Tel: 0161 611 4059

Guildford Breast Screening Training Centre
Jarvis Screening Centre
Stoughton Road
Guildford
GU1 1LJ

Tel: 01483 783260

Breast Screening Training Unit
King's College Hospital
Denmark Hill
Camberwell
London
SE5 9RS

Tel: 020 7346 3870

Breast Screening Training School
Duchess of Kent Breast Screening Unit
St George's Hospital
205 Blackshaw Road
Tooting
London
SW17 0BZ

Tel: 020 8725 1534

APPENDIX 5: NHSBSP GUIDELINES ON QA VISITS – RADIOLOGY

Introduction

Radiological performance should be measured routinely as part of the NHSBSP QA programme. This document describes the key steps to be followed by the regional QA radiologist together with the regional QA team in

- i. assessing the performance of both the radiology team and the individuals involved in screen reading and assessment, including radiologists, breast clinicians and consultant/advanced radiographic practitioners
- ii. identifying radiological underperformance and acting to rectify it constructively and effectively to ensure that high standards of radiological practice within the NHSBSP are maintained.

This document should be read in conjunction with the *Quality Assurance Guidelines for Breast Cancer Screening Radiology*.

All those involved in reading screening mammograms or in the radiological assessment of screen-detected abnormalities should participate in the QA audit of breast screening radiology (eg radiologists, radiographers and breast clinicians).

Assessing radiological performance

Radiological performance in breast screening is assessed through examination of data, peer review of selected cases, attendance at a multidisciplinary meeting and discussion with the radiology team.

1 Data review

The QA radiologists should review the following

<ul style="list-style-type: none"> • Core radiological quality standards* • General radiological quality standards • Non-operative diagnostic procedures* • Service quality standards* • Interval cancer rates* 	Compare with NHSBSP QA standards
<ul style="list-style-type: none"> • Individual's screen reading performance* 	Film reader QA report
<ul style="list-style-type: none"> • Record of individual's attendance at multidisciplinary meetings (MDMs) 	

-
- Breast screening training professional development/CME
 - participation in PERFORMS
 - Job plan (including time spent screen reading, undertaking assessment, attending MDMs) Data to be supplied by each individual
 - Date of last formal appraisal
 - Audit activity
-

Unit work instructions and protocols for screen reading and assessment

Equipment/equipment replacement programme

*Data relating to these standards for the last three complete screening years (annual plus amalgamated three-year data) should be available to the visiting QA radiologist at least three weeks prior to the QA visit. It is the responsibility of the director of the screening service, supported by the regional QARC, to ensure that this information is available and has been carefully checked for accuracy and completeness by staff from QARC and the screening programme. Identifiable individual performance data should be disclosed only to the director of the breast screening programme and the visiting QA radiologist.

2 Peer review of screening cases

The purpose of the QA visit is not only to assess performance as documented in the above data and statistics but also to review practice. This may be achieved through peer review of cases and by attendance at the unit's MDM.

It is recognised that the process of peer review is potentially time consuming and in larger centres, or where there are concerns about the unit's performance, it is likely to take more than one day. The case review will normally need to be undertaken on a separate day in advance of the main multidisciplinary QA visit.

Mandatory cases for review

- i. Interval cancers. The aim of this review is to ensure that interval cancers are being classified appropriately as category 1, 2 or 3, that a system is in place for identifying and processing interval cancers, and that documentation is adequate. The QA radiologist should identify the sample size required for review. All cases identified as 'false negative assessment' presenting as interval cancers or cancers detected at a subsequent screening episode must be reviewed
- ii. Films and records of all women seen at one assessment clinic for each assessment radiology lead (radiologist, breast clinician or advanced practitioner). A minimum of three assessment clinics per centre should be reviewed. The QA radiologist should choose the clinics to be reviewed from the previous six months. A clinic list should be provided and reasons given for any cases unavailable for review
- iii. Films and records of all women in whom cancer has been diagnosed in the previous three years while on short-term review
- iv. Films and records of all women placed on short-term recall for a second time
- v. All cases of failed localisation in the previous year. Failure may have resulted because the lesion could no longer be identified and localisation was abandoned or because localisation was carried out but the intended lesion was not excised

Supplementary cases for review

Following review of the data the QA radiologist may wish to review a selection from the following groups of cases

- vi. Films and records of the last 20 women placed on short-term recall
- vii. Films and records of women in whom a pre-operative diagnosis of malignancy was not made
- viii. Films and records of the last 20 women who underwent more than one needle biopsy procedure per radiological malignant lesion
- ix. Films and records of the last 20 women who underwent a benign biopsy
- x. Review of cancers detected by only one of two readers
- xi. If the non-operative diagnosis rate for DCIS is low (<80%) each individual's needle biopsy accuracy should be reviewed (ie cancers with B1/B2 cores and calcification retrieval rates).

3 Multidisciplinary QA visit day

Reviewing and discussing the unit's data

The QA radiologist should review and discuss the unit's data with the local radiology team. Data indicating a high level of performance compared with published standards and targets should be identified as well as data indicating possible areas of activity where radiology performance could or should be improved.

It is suggested that the QA radiologist ask the team the following questions

- How is screen reading undertaken (by single or double reading, consensus or arbitration etc)?
- Is there adequate protected sessional time for screen reading without interruption?
- Does the opinion of all readers have equal status?
- Do new readers avoid reading with other new readers?
- Is there adequate equipment?
- How is the 'right result' recorded?

The QA radiologist should also ascertain how assessment is undertaken

- How many clinics are undertaken per week?
- Which staff attend?
- Are all biopsies done at a single attendance?

It is suggested that the QA radiologist ask open questions such as 'How do you do stereotactic biopsy?'

Information should also be sought on multidisciplinary meetings

- Are all cases in which a needle biopsy has been undertaken discussed?
- Are all women placed on short-term recall following assessment discussed?
- Are there appropriate facilities and equipment plus protected time for MDM discussion?
- Are MDM management decisions adequately documented?

The QA radiologist may wish to discuss the results of local audits, the unit's participation in research, and issues relating to breast screening training.

It may be illuminating to ask the radiology team about the perceived strengths and weaknesses of their unit, what they have achieved and what additional support they need to help them work more effectively.

Radiology training

The local radiologists' previous training and CME records should be reviewed. Guidance on the content of a training programme and CME requirements is given in Appendices 2 and 3 of *Quality Assurance Guidelines for Breast Cancer Screening Radiology*, NHSBSP Publication No 59. This advises that professionals who are not radiologists but who undertake radiological procedures should follow the same guidance but should refer to their own specialist professional groups for details of specific training needs.

The recommended curriculum includes both theoretical training and practical training in a multi-disciplinary setting. It also requires supervision by a radiologist with extensive experience in breast imaging. National training centres are listed in Appendix 4 of the *Quality Assurance Guidelines for Breast Cancer Screening Radiology*. Training can be delivered locally provided it follows the recommended curriculum. If there is evidence of poor training then this should be rectified immediately.

Attendance at regular update meetings should also be reviewed: these include RCR breast group meetings, Symposium Mammographicum etc. It is suggested that around 25% of a screening radiologist's allotted time (currently 12.5 hours per year) be dedicated specifically to breast-related education and that a significant proportion of this activity be undertaken at national meetings.

It is recommended in the *Quality Assurance Guidelines for Breast Cancer Screening Radiology* that film readers be encouraged to participate in the voluntary PERFORMS self-assessment programme, administered by the University of Loughborough. If this has not been done recently, then participation should be strongly encouraged and the reader(s) should take action on any deficiencies identified. Participation should be reported.

QA radiologist report

Information gathered from analysis of the unit's data as measured against published standards, plus information gained through peer review and discussion with the radiology team on the day of the QA visit, should together enable the QA radiologist to decide whether the standard of radiological performance in the screening unit is satisfactory.

The QA radiologist should then report either

- i. that there is a satisfactory standard of radiological performance in the screening programme or
- ii. that there is a possible problem of radiological underperformance in the screening programme.

4 Identifying underperformance and acting to ensure that satisfactory radiology standards are achieved

There are two main areas of possible radiological underperformance

- i. at screen reading: repeated failure to recognise or interpret signs of malignancy
- ii. at assessment: failure to carry out the investigation needed to establish a definitive diagnosis or determine further management of the case.

Actions may be recommended after the QA visit.

Action: Stage 1

The QA radiologist must clearly identify the area of radiological underperformance and at this stage should inform the QA director. The QA radiologist, in conjunction with the QA director, the local radiologists and the director of the screening programme, should decide on a clearly defined plan of action to address the problem. This plan should relate to the area of underperformance identified by the QA radiologist. In most cases, the problem should be effectively addressed at local/regional level and may involve a period of problem-specific training at one of the national breast screening training centres. A proposed training programme should be discussed and agreed with the individual, the training centre and the host Trust. The proposed plan of action should be clearly documented and should specify a timescale. It should also include a repeat review of relevant data and/or cases by the QA radiologist to ensure that satisfactory radiological standards are being achieved.

Following the repeat review, and after completion of the plan of action and any additional training, the QA radiologist should report to the QA director either (a) that a satisfactory standard of radiological performance is now being achieved in the screening programme or (b) that there remains a problem of radiological underperformance. If (b), the QA radiologist and QA director should recommend action stage 2.

Action: Stage 2

Stage 2 involves a more detailed review of radiological practice within the screening programme, together with on-site training. To ensure that the screening service continues, an independent radiologist of proven screening ability should be recruited to double read all screening films and attend screening assessment clinics in parallel with the local radiological team. This external radiologist should be selected with the agreement of the local team and should have a formal contract with the provider unit to function fully as a breast screening radiologist, with the authority to recall patients for assessment and carry out assessment procedures. This ensures that the screening service is not compromised while investigation of possibly poor radiological performance is carried out. If it is not possible to recruit an external radiologist to perform this function, suspension of screening may need to be considered. However this must be regarded as a last resort.

The process of shadowing and double reading will allow the external radiologist to identify any obvious current areas of underperformance. At the same time, the external radiologist should undertake a review of previous practice. Previous experience suggests that these retrospective reviews are best carried out by two external radiologists (such as the regional radiology coordinator and a radiologist from outside the region) to facilitate double reading and consensus review. Initially this review should involve

- all cases currently placed on short-term recall
- all cases recalled for assessment over the previous two years (as a measure of assessment decision making)
- all interval cancers identified over the previous five years (as an indication of screen reading performance). However review of interval cancers is a relevant and reliable indicator only if data on them are robust and have been properly collected – a low interval cancer rate may mean poor data collection.

The process of double reading, assessment, shadowing and review of previous outcomes may identify particular problems of radiological interpretation. These can be addressed either locally by the external radiologist or by targeting the area in which the problem has arisen via secondment to a national breast screening training centre. The QA director should ensure that the chief executive of the Trust, the Regional Director of Public Health, the chief executive of the Strategic Health Authority and the national breast screening coordinator are all informed that a stage 2 review and training process is taking place. This process should be agreed in writing with the clinical director of the screening programme with a clear timescale. Provision of resources, including (if necessary) funding for the external consultant radiologist sessions and expenses, should be the responsibility of the screening programme's Trust. The QA director, in consultation with the external radiologist, the QA radiologist, the local radiologists and the director of the screening programme, must decide at the end of the stage 2 process whether it has been effective in addressing the radiological problems identified in the screening programme. It is anticipated that these problems will have been effectively addressed, enabling the screening service to continue with satisfactory high standards. The date of the next QA visit should then be agreed.

Action: Stage 3

However if the QA director, the external radiologist and the QA radiologist decide that a satisfactory standard of radiological performance cannot be achieved, they should recommend suspension of the individual from the screening programme. If, as a result, the service becomes single handed, suspension of screening should be recommended until alternative arrangements for providing screen reading and/or screening assessment can be arranged.

