



# BEST PRACTISE GUIDELINES

## FOR SURGEONS IN BREAST CANCER SCREENING

**Editors:**

Sarah Downey  
Leena Chagla  
Vidya Chandran  
Ashu Gandhi  
Graham Layer  
Ajay Sahu  
Mark Sibbering

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## 1. INTRODUCTION

The NHS Breast Screening Programme (NHSBSP) has been a quality assured programme from the outset. It has always endeavoured, through its quality assurance initiatives, to ensure that women receive the same high standards of care and diagnosis wherever they live, and that standards are constantly improving. The first quality assurance guidelines for surgeons working with the NHSBSP were produced in 1992 by the Breast Surgeons Group at BASO with updated editions published in 1997 and 2002. The Association of Breast Surgery at BASO published updated guidelines in 2009.

These updated guidelines from the Association of Breast Surgery (ABS) aim to:

- identify appropriate measures of quality and effectiveness of diagnosis and treatment provided for screen-detected breast cancer
- facilitate and support the implementation of continuous quality assurance and improvement mechanisms
- define standards for assessment of the service provided
- be consistent with wider NHS initiatives

Ultimately the screening process can only be successful if it is followed by timely and appropriate management of the detected breast cancers by the multidisciplinary team (MDT). The quality assurance objectives and targets within this document are those that directly involve surgeons.

The management of breast cancer from the point of diagnosis to discharge from follow up should essentially be the same, whether the cancer is detected via breast screening or as the result of the investigation of breast symptoms. These updated Quality Assurance Guidelines for Surgeons in Breast Cancer Screening reflect this and concentrate on the screening process up to the point of diagnosis and issues specific to the NHSBSP. They should be used in conjunction with the Association of Breast Surgery Guidance Platform available on their website: [www.associationofbreastsurgery.org.uk](http://www.associationofbreastsurgery.org.uk)

The guidelines are addressed principally to surgeons working within the screening programme, who will use them to audit their own activity. They will assist the regional quality assurance teams and others outside the surgeon's immediate colleagues in the assessment of the quality of breast surgery afforded by a screening unit. They may also be of help to Trusts and Cancer Networks in identifying the resources and skills required to ensure that women with screen-detected breast cancer are cared for optimally.

## 2. ASSESSMENT

This guidance should be used in conjunction with the updated Clinical guidance for breast cancer screening assessment which can be found on the ABS Guidance Platform available on their website.

### 2.1 Assessment clinics

Most screen detected abnormalities are impalpable; therefore the assessment process is directed by the responsible assessor who must be an accredited breast radiologist, consultant radiographer or breast clinician.

The clinical examination of any woman recalled for assessment for a clinical reason should be carried out prior to any biopsy. The examination should be carried out by an individual who has the necessary clinical skills, according to local protocols.

Any woman who has undergone needle biopsy should have her result discussed in a multidisciplinary team meeting (MDM) and her management options agreed before receiving her result and discussing those options.

### 2.2 Multidisciplinary meetings

Attendance at the multidisciplinary team meeting (MDM) is crucial for all involved in Breast Screening. Core membership for all MDMs involving Breast Screening patients should include a surgeon. This is an essential part of the diagnostic and treatment process.

A MDM to discuss the results of screening assessment should occur at least weekly. Effective MDMs are patient centred although the format and composition of their attendance will vary between different screening units. It should consider all cases from the assessment clinic where a needle biopsy has been carried out and those in which return to routine screening is not the obvious outcome. A record of those who attend MDMs and the minutes of those meetings must be retained within each screening unit. The record should include one consistent clinical outcome agreed by all members of the MDT present and a copy of that outcome should be part of an individual patient's notes. The minutes of the meetings and register of attendances and should be available for review at any quality assurance visit.

It is an important principle, however, that each patient referred for surgery should be discussed at an MDM in the presence of the recipient surgeon or their representative before treatment options are discussed with the patient. Local interpretation of this policy may differ between units, depending on resource logistics.

### 2.3 Assessment Biopsy Results

If a needle biopsy has been carried out the woman should be given the biopsy result in one week (5 working days) or less.

Even for a normal result, the provisional and final results of assessment should be given to the patient by a clinical practitioner. All women who have been assessed and do not have a diagnosis of cancer should receive written confirmation of the outcome of their assessment.

All women with a diagnosis of breast cancer should receive their results in the presence of a clinician and a clinical nurse specialist in breast care. Enough time should be allocated to provide the necessary counselling and support.

If not seen by a surgeon at that time, those women who require a surgical opinion should be reviewed by the surgeon within one week (5 working days). Local guidelines should be agreed to ensure that there are no undue delays between radiological and surgical assessment.

### 3. DIAGNOSTIC BIOPSY

#### 3.1 Non-operative needle biopsy

A non-operative diagnosis is desirable as it allows a full and frank discussion of all treatment options prior to surgery. Figures from the 2015-16 NHSBSP / ABS audit of screen-detected cancers indicate that a non-operative diagnosis was achieved in 97% of cases. It is recognised that for invasive cancers a higher non-operative diagnosis rate is achievable, and in this audit 99% of invasive cases were diagnosed non-operatively. Although more difficult to achieve, non-operative diagnosis of in situ cases continues to improve and was 92% in 2015-16. In most cases, needle biopsy of apparently benign lesions will help to avoid unnecessary surgery. An operative biopsy will not be required to obtain a diagnosis for the vast majority of women attending for screening assessment.

At the multidisciplinary team (MDT) meeting it is important that the correlation between imaging/clinical findings and pathology is checked as part of the triple assessment process. If there is discordance between the imaging/clinical and pathology outcomes then further action should be discussed by the MDT, such as a repeat needle biopsy. This consideration is particularly important in women with an initial B4 result.

A small number of screen-detected breast lesions will be assessed as B3 (of uncertain malignant potential) on needle core biopsy. The updated 'Clinical guidance for breast cancer screening assessment' includes guidance on the standardisation of clinical management of B3 lesions. When deciding whether to undertake vacuum-assisted excision (VAE) or diagnostic surgery, the MDT should specifically consider how representative the sampling is and the degree of pathology concern.

Although every effort must be made to establish a non-operative diagnosis, excessive delay by repeated attempts at diagnosis by needle biopsy should also be avoided. It is recommended that needle biopsy should be performed on a maximum of two occasions on the same breast lesion. Some patients may require additional procedures as part of the diagnostic work up after a malignant diagnosis has been confirmed e.g. multifocal disease suspected, following MRI, to assess suspected axillary lymph node involvement etc. If additional needle biopsies result from this they should be carried out in a timely fashion (aiming for 5 working days).

#### 3.2 Operative diagnostic biopsy

Operative diagnostic biopsies, also described as open surgical biopsies, are carried out specifically for the purpose of establishing a diagnosis in patients with inconclusive needle biopsy results. Definitive therapeutic surgical procedures or any additional procedures such as lymph node staging should not be carried out at the same time, unless there is a proven malignant diagnosis for a separate breast lesion. Every effort should be made to minimise cosmetic impairment by appropriate placement of incisions, accurate identification of lesions and avoidance of removal of large amounts of normal breast tissue.

##### **Localisation**

Radiological markers must be accurately placed. If ultrasound guided skin marking is used, it should be placed with the patient positioned in the 'operating position' and the position, depth and size of the lesion clearly recorded.

##### **Specimen Imaging**

Confirmation of identification should be made by specimen radiography. Dedicated equipment (eg. digital specimen radiography cabinet) should be available so that a radiograph can be taken of the specimen and reported to or by the surgeon within 20 minutes. Specimen ultrasound may be useful in those lesions which are not easily visible radiographically. Interpretation of specimen radiographs must be clearly recorded. If this is done by the operating surgeon, the result must be confirmed by the radiologist at the subsequent multidisciplinary team meeting. If the radiologist reports the image at once, no more than 20 minutes should elapse before the report is received by the operating surgeon.

**Frozen section pathology**

Frozen sections with immediate pathological reporting at surgical breast biopsy should not be performed except in very unusual circumstances and the reasons for this documented in the patient's case notes. If this is the case, each occasion should be available for audit at the quality assurance (QA) visit.

**Weight of biopsy specimens**

The fresh weight of tissue removed for all cases where a diagnostic open biopsy is performed should be recorded in the patient's notes. All lesions not correctly identified at the first operation and all biopsies for what proves to be benign disease weighing more than 40g should be discussed at the MDM and any mitigating reasons recorded. All such cases should be available for review at the next QA visit.

**Table 3: Standards for open biopsy**

Objective	Outcome measure
To minimise the cosmetic impairment of diagnostic open biopsy	The fresh weight of tissue removed for all cases where a diagnostic open biopsy is performed should be recorded
	> 90% of open surgical biopsies carried out for diagnosis which prove to be benign should weigh $\leq$ 20g
	All cases where open surgical diagnostic biopsies which prove to be benign and weigh >40g should be discussed at the post-operative MDT meeting and any mitigating reasons recorded. These cases should be reviewed at the next QA visit.
To ensure the diagnostic accuracy of open biopsy	>98% of impalpable lesions should be correctly identified at the first operation

## 4. SCREENING SPECIFIC SURGICAL REQUIREMENTS

### 4.1 Surgeon's screening caseload

Each surgeon involved in the NHS BSP should maintain a surgical caseload of at least 10 screen-detected cancers per year, averaged over a three year period. It is expected that surgeons with low caseloads should be able to demonstrate an annual surgical workload of at least 30 treated breast cancers (screen-detected and symptomatic). Outcomes for surgeons with particularly low or very high annual caseloads may be subject to particular review to ensure that practise meets the screening standards.

For each woman in the NHSBSP & ABS audit of screen detected cancers, one surgeon is recorded as the main person responsible for the case. Many surgeons now work in teams and it is possible that a woman may have seen or have been treated by more than one consultant surgeon during her cancer journey, while only one surgeon has been recorded on the National Breast Screening Computer System. The surgeon who undertakes the primary therapeutic procedure should be recorded as the responsible clinician in the audit. The caseload for some surgeons may include patients operated on by associate specialists or supervised trainees. If a non-consultant grade surgeon is practising independently within the team, their data should be collated under their GMC number and audited as primary responsible surgeon. The lead surgeon is responsible for ensuring that all independent practitioners within a unit are listed with the SQAS team.

### 4.2 Waiting Times

Waiting times for surgery should be kept to a minimum following the decision to operate,

#### a. Breast Cancer Treatment

Women with breast cancer detected through the NHSBSP must commence treatment within two months (62 days) of the date of the decision to recall them for assessment. There should be a maximum one month (31 day) wait from the date of diagnosis (interpreted as date of decision to treat) to the date of the first definitive treatment for all cancers.

#### b. Diagnostic Open Surgical Biopsy

Short waiting times between the various aspects of the diagnostic process will help to minimise patient anxiety as well as assisting in meeting waiting time targets. Such biopsies will need to be carried out promptly in order to achieve the 62 day target for those that subsequently prove to be malignant, and this is also consistent with the diagnostic open surgical biopsy waiting time target for symptomatic patients.

#### c. Benign Surgery (non-diagnostic)

For patients having surgical removal of a pathologically proven benign lesion standard non-cancer NHS target waiting times will apply.

**Table 1: NHSBSP waiting time standards relevant to assessment and surgery**

Objective	Criteria	Minimum standard	Target standard
To minimise the delay for women awaiting the results of non-operative biopsies	Proportion of women for whom the time interval between non-operative biopsy and the result being given to the patient is one week or less	≥90%	100%
To minimise the delay for women who require surgical assessment	Proportion of women for whom the time interval between the decision to refer to a surgeon and surgical assessment is one week or less	≥90%	100%

### 4.3 Specific facilities required for the surgery in the NHSBSP

#### **Localisation service for impalpable lesions**

In order to carry out surgery for impalpable breast lesions the surgical service requires a clear pathway for pre-operative localisation of breast lesions. This should be described in local protocols.

Placement of marker wires under x-ray or ultrasound guidance is the most commonly used method. Radio-guided occult lesion localisation (ROLL) is also a recognised method of localisation used in a number of screening services. Any new method of localisation introduced should be the subject of an approved research trial or approved audit of practice demonstrating equivalent results to current techniques before routine implementation.

#### **Specimen radiography**

This is a requirement for confirmation of removal of impalpable radiological lesions.

#### **Sentinel lymph node biopsy**

This should be a standard procedure undertaken by the surgical service. The combined blue dye / radioisotope technique is a recommended axillary staging procedure for the majority of patients with early invasive breast cancer. Intra-operative analysis is not a requirement.

## 5. TREATMENT OF SCREEN-DETECTED BREAST CANCER

Surgeons involved in the treatment of screen-detected breast cancer must be aware of all treatment options available. Women with screen-detected breast cancer generally present with earlier stage disease and with a higher proportion of DCIS than in symptomatic practice. However, once diagnosed the treatment options are the same irrespective of the route of diagnosis. Surgeons treating patients from the screening programme should work to surgical guidelines available on the ABS Guidance Platform on their website.

## 6. QUALITY ASSURANCE (QA)

The NHSBSP is a quality assured programme across the UK. Different processes for audit and quality assurance apply in the different nations that make up the United Kingdom.

In England, the breast screening pathway begins with the identification of eligible women through batch specification and includes mammography, the assessment of presumptive signs of malignancy, diagnostic and therapeutic surgery and pathology. The screening programme ends with the diagnosis of cancer or the completion of the screening programme at 70 years of age. Breast screening QA is described in the Programme Specific Operating Model for Breast Screening QA and includes the surgeon's role in the diagnosis and management of screen-detected cancers. ([www.gov.uk](http://www.gov.uk))

In order to deliver quality assurance, an infrastructure was established in the early years of the programme that has been adapted as the NHS and healthcare has evolved, but which has shown increasing strength. It has contributed to improving the standard of care offered to all women diagnosed with breast cancer.

Public Health England (PHE) now has responsibility for the quality assurance of screening programmes in England. Heads of QA in each region appoint a multidisciplinary QA team, including a lead surgeon who acts as the Professional Clinical Advisor for surgical aspects of breast screening quality assurance.

### 6.1 Surgical Quality Assurance

#### Professional and Clinical Advisor for Surgery

For each geographical region, surgeons are appointed as Regional Professional Clinical Advisors (PCAs)

PCAs may be asked to assist in a number of different QA activities including:

- Expert advice to the Screening Quality Assurance Service (SQAS) on the screening programme as it pertains to their professional area (Surgery)
- QA visits (including preparation and reporting time)
- Desk Top Reviews of evidence where applicable
- Pre-visit work or observations
- Participation in national project groups, workshops etc.
- Regional SQAS meetings
- Support / advice in screening incidents
- Other ad hoc QA activities

The role of PCAs in the QA process is to provide expert, impartial advice on their professional area. Any views expressed must reflect the most recent standards, service specifications and any contemporaneous guidelines produced by the screening programme or relevant professional bodies.

PCAs should not provide advice which could be construed as a formal second opinion on individual cases that will/could impact on the outcome of care of an individual patient.

The PCA, with assistance from SQAS, will convene at least one annual meeting of all the surgeons within the region involved in breast screening, to discuss surgical performance data.

### Regional QA Groups

There are two interlinked groups at a regional level which involve surgeons:

- a group comprising all surgeons involved with screening within a region; the surgical PCA appointed by PHE chairs this group. Regular attendance (at least 50% of meetings) is expected by all surgeons involved in treating women with screen detected breast cancer.
- a multidisciplinary regional QA team comprising the PCAs of the individual professional groups; this group is the forum for the overall assessment of the programme in the region and the team will visit individual units to assess quality. The lead screening surgeon for each unit visited should be available to discuss surgical data at the time of the visit.

### Screening Surgeons

The NHSBSP is a quality assured programme. Thus any surgeon participating in the programme and treating screening patients must participate with quality assurance initiatives that apply to the surgeon's role. This includes working as part of the screening team locally and also as part of the regional screening surgeons group. A breast screening surgeon should pay special attention to cooperation and participation with data collection exercises and professional training where regular participation is expected. In addition, the lead surgeon in a breast screening unit takes on particular responsibilities which are described below.

#### a) Professional Updates and Liaison

All surgeons involved in the NHSBSP should normally be present at more than 50% of meetings of the regional screening surgeons' group in a 3 year period and at least 50% of all relevant meetings in a 3 year cycle. These are the regional screening surgeons' meeting, the annual ABS Conference where the national screening audit data is presented and QA visits to their breast screening unit. Regular visits by the QA Team to each screening unit are an important part of the QA process and individual surgeons are expected to demonstrate active involvement in this essential process and a clear commitment to audit and quality assurance.

#### b) Data Collection and Audit

The NHSBSP has established a major audit series in which surgeons have played a highly significant role. Each screening service is routinely audited through these, which include aggregated clinical information on every woman invited and screened by the NHSBSP in any given year. The surgical contribution is an essential component of this data collection and audit exercise.

In addition the ABS has for some years worked with the NHSBSP to produce annual audits of treatment and survival of women with screen-detected breast cancers. These have become the pre-eminent audits of breast cancer treatment.

Participation in the NHSBSP / ABS audit is required of all surgeons working with the NHSBSP. Only by such participation can outcome measures be accurately monitored and improved with time. Each individual surgeon is responsible for ensuring the quality of relevant surgical data included in screening audits. However, it is recognised that appropriate IT or administrative support will be required for this responsibility to be discharged effectively.

#### c) Duty of Candour and Disclosure of Audit

In addition, in their symptomatic practice, surgeons will identify breast cancers in women between scheduled NHSBSP screens. Identification and audit of these interval cancers is an essential part of monitoring and evaluation of the NHSBSP and another area where surgical involvement and commitment to the process of data collection is vital. Interval Cancer guidance is outlined in the documentation published by PHE via the following link: [www.gov.uk](http://www.gov.uk)

Women, who are diagnosed with interval cancers, are entitled, if they wish this, to be informed of the outcome of the review of the interval cancer conducted by the screening unit. Public Health England have produced guidance for screening and symptomatic units on how to manage this legal requirement of Duty of Candour and Disclosure of Audit. The guidance can be found on their website: [www.gov.uk](http://www.gov.uk)

**d) Training**

The management of patients requiring surgery as a result of the screening programme should only be carried out by surgeons who have acquired the necessary specialist knowledge and skills. This should be assessed as part of the appointment process of a Consultant Surgeon at a breast screening service.

All surgeons newly taking up a consultant post with a commitment to treating screen detected breast cancers should, during their training, have worked in a Breast Unit that regularly manages screen detected breast cancers and have attended regular MDT meetings together with assessment and results clinics.

There may be occasions when an established consultant wishes to, or is asked to accept a screening commitment as part of a change in their job plan. In such circumstances they should have time allocated to allow them to work alongside another established breast screening surgeon and attend the MDT meetings in addition to clinics. This should occur prior to commencing regular independent sessions, in order to become familiar with current breast screening practice.

**e) Lead Surgeon in a Breast Screening Unit**

For each breast screening unit, one surgeon should be nominated and formally appointed as the lead surgeon responsible for ensuring the quality of treatment for patients with screen-detected breast cancer from that unit. This includes making sure that all relevant surgeons have attended appropriate training and update courses, participate in the expected number of regional educational and audit activities and support accurate submission of all relevant audit data. In particular, the surgeon nominated as the lead surgeon is responsible for ensuring the collection, entry and retrieval of data by surgeons treating patients with screen-detected breast cancer from that unit. The lead surgeon must be able to confirm the validity of data supplied by surgeons within the unit.

**Assessment of surgical performance in the breast screening programme**

The surgeon is a member of the multidisciplinary breast screening team responsible for achieving the national objectives set for the NHSBSP. Some of these objectives are outside the influence of the surgeon alone, but meeting the objectives is essential to providing a high quality service, which is of significant benefit to women.

**a) Routine audit of surgical performance**

Surgical performance in breast screening is measured routinely by the regular review of data on biopsy and management of each case of breast cancer diagnosed by a breast screening unit. As described above, one surgeon in each unit is responsible for that unit's surgical data collection and audit. Participation in the NHSBSP / ABS audit is compulsory, and audit details for each unit must be reported and discussed at least annually at a meeting of the regional screening surgeons' group convened by the regional PCA for Surgery. The SQAS will check that the unit's surgeons are participating in the NHSBSP / ABS audit and in the regional review of audit data.

**b) Assessment of surgical performance**

In addition to routine audit and regular review by the breast screening surgeons of their own surgical QA data, surgical performance will be assessed as part of the QA visit. The QA visit will address the wider issues of assessment and management of women with screen-detected cancers.

There is an ongoing process to standardise the format of QA visits in England. These are available on the Public Health England website, [www.gov.uk](http://www.gov.uk)

## 7. ACHIEVING THE OBJECTIVES AS A NATIONAL PROGRAMME

### 7.1 Professional Liaison

The Royal Colleges of Surgeons are responsible for the quality of professional standards and for the approval of training programmes, training centres and courses. The ABS advises the Royal Colleges on the following:

- core curriculum for training on breast screening
- structure of courses
- standards of performance in screening
- guidelines for surgical quality assurance.

The ABS has the responsibility to:

- review the surgical results of the NHSBSP on an annual basis
- collate experience gained relating to the diagnosis and treatment of screen-detected lesions
- propose changes in the surgical quality objectives and standards in the light of experience
- advise on surgical problems arising in individual breast screening units.

### 7.2 Clinical Trials and Prospective Studies

Surgeons are encouraged to offer all eligible women an appropriate trial or study. The NCRI Breast Clinical Studies Group portfolio of all open trials and can be found at [www.ncri.org.uk](http://www.ncri.org.uk)

In addition PHE sponsors and supports The Sloane Project ([www.sloanproject.co.uk](http://www.sloanproject.co.uk)) which aims to include all cases of in situ disease and atypical hyperplasias diagnosed in the NHSBSP.



at The Royal College of Surgeons  
35 – 43 Lincoln's Inn Fields  
London WC2A 3PE

[www.associationofbreastsurgery.org.uk](http://www.associationofbreastsurgery.org.uk)