

**QUALITY ASSURANCE GUIDELINES FOR  
SURGEONS IN BREAST CANCER SCREENING**

**National Coordinating Group for Surgeons in  
Breast Cancer Screening working with the  
Association of Breast Surgery at BASO**

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## **ACKNOWLEDGEMENTS**

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## 1. INTRODUCTION

*The NHS Plan* identifies cancer, its diagnosis and its treatment as one of the priorities for the NHS.<sup>1</sup> *The NHS Cancer Plan*, which was published in September 2000, identifies issues within the treatment of cancer that need to be addressed.<sup>2</sup> These include the widespread geographical inequalities in the quality and type of treatment that patients receive. The NHS Breast Screening Programme (NHSBSP) has always endeavoured, through its quality assurance initiative, to ensure that women suspected of having breast cancer after attending an initial mammogram receive the same high standard of care, and ultimately of diagnosis, wherever they live. In 1992, the Breast Surgeons Group at BASO (now the Association of Breast Surgery at BASO) was involved in the compilation of guidelines and an outline of preferred practice for the diagnosis and management of women with screen-detected breast cancer.<sup>3</sup> These quality assurance guidelines for surgeons working within breast cancer screening are intended as an update to those previously published and are part of that quality assurance initiative. They aim to:

- identify appropriate measures of quality and effectiveness of treatment provided for screen-detected breast cancer
- facilitate and support the implementation of a continuous quality assurance mechanism
- define standards for assessment of the service provided.

The screening process can only prove ultimately successful if it is followed by timely and appropriate management by surgeons of breast cancers found. The quality assurance objectives and targets within this document are those that directly involve surgeons. However, the surgeon is a member of a multidisciplinary team, and these guidelines fit within the overall quality assurance process as the surgeon fits within that overall team.

The guidelines are addressed principally to surgeons working within the screening programme, who will use them in a personal capacity 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 some help to trust chief executives and cancer networks in identifying the resources and skills needed so that women with screen-detected breast cancer are cared for in as optimal a manner as possible.

## 2. ASSESSMENT

### 2.1 Assessment clinics

Most screen-detected abnormalities are impalpable, therefore the assessment process is directed by radiologists. The results of assessment, including needle biopsy results, must be discussed at the weekly multidisciplinary team (MDT) meeting (see 2.2).

For women who are diagnosed non-operatively, the time interval between non-operative biopsy and result should be one week or less. Needle biopsy results should be discussed with the woman in the presence of a breast care nurse. Ideally, the surgeon should attend the assessment clinic.

For women who require surgical assessment, the time interval between the decision to refer to a surgeon and surgical assessment should be one week or less. Ideally, the surgeon should attend the assessment clinic.

Waiting times for surgery must be kept to a minimum following the decision to operate, and women must be admitted for treatment within two months of their first assessment visit. It is acknowledged that if mastectomy with primary reconstruction is performed this may lead to a significant delay. Sometimes, delays in surgery may be at the request of the patient, and it is important that the reasons for any delay in surgery beyond the minimum standard should be clearly documented.

The revised national standards relevant to assessment and surgery are shown in Table 1.

**Table 1** Revised national standards relevant to assessment and surgery

Objective	Criteria	Minimum standard	Target
14. 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%
15. 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%
16. To minimise any delay for women who require treatment for screen-detected breast cancer	The percentage of women who are admitted for treatment within two months of their first assessment visit	≥ 90%	100%

Within these national standards, the more detailed surgical quality objectives are as follows:

<b>Quality objective</b>	<b>Outcome measure</b>
To minimise the interval from decision that diagnostic surgery is required to date of diagnostic surgery	≥ 90% should be admitted within 2 weeks
To minimise the interval from date of diagnosis to date of therapeutic surgery	100% should be admitted within 4 weeks

The definition of the date of diagnosis agreed by the Association of Breast Surgery at BASO is the date the first definitive cytology or core biopsy that gave a malignant result (C5 or B5) was performed.

### **2.2 Multidisciplinary meetings**

Attendance at the multidisciplinary team meeting (MDT) is crucial for all involved. This is part of the diagnostic and treatment process, and the MDT meeting should be held prospectively on a weekly basis. It should consider all cases from the assessment clinic for whom return to routine screening is not the obvious outcome. Further guidance is given in *Clinical Guidelines for Breast Cancer Screening Assessment*.<sup>4</sup>

A record of those who attend MDT meetings and the minutes of those meetings, including the actions agreed, must be retained within each screening unit. The record of attendances and the minutes of the meetings should be available for inspection on any quality assurance visit. The MDT meetings are patient centred and their format and the composition of the attendance will vary through different screening units. It is an important principle, however, that each patient referred for surgery should be discussed at an MDT meeting in the presence of the recipient surgeon or their representative prior to the patient's surgery.

### 3. DIAGNOSIS

#### 3.1 Preoperative biopsy

A preoperative diagnosis is desirable as it allows a full and frank discussion of all treatment options prior to surgery. In most cases, needle biopsy of apparently benign lesions will help to avoid unnecessary surgery.

A significant number of screen-detected lesions will be borderline on the basis of imaging and needle biopsy. Although every effort must be made to establish a preoperative diagnosis, excessive delay by repeated attempts at diagnosis by needle biopsy should be avoided. It is recommended that needle biopsy should be performed on no more than two occasions. If diagnosis is still not established, surgical biopsy should be performed.

#### Objective

To minimise unnecessary surgery, ie open surgical biopsies that prove to be benign

Benign open diagnostic biopsies should be

#### Outcome measure

More than 80% of all cancers should have preoperative pathological diagnosis

< 15 per 10 000 prevalent screen

< 10 per 10 000 incident screen

#### 3.2 Operative biopsy

Open biopsies are carried out specifically for the purpose of establishing a diagnosis. Additional procedures such as lymph node sampling should not be carried out at the same time. Every effort should be made to minimise cosmetic impairment. To this end, 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 lesion depth clearly recorded. Specimen radiographs to confirm identification of the lesion should not unduly lengthen the operating time. Interpretation of the specimen radiograph must be clearly recorded. If this is done by the operating surgeon, the result must be confirmed by the radiologist at the multidisciplinary meeting. If the radiologist reports the film at once, no more than 30 minutes should elapse before the reported film is received by the operating surgeon.

#### Objective

To maximise the identification of mammography-detected lesions

To minimise the cosmetic impairment of open biopsy

To improve the diagnostic accuracy of open biopsy

#### Outcome measure

> 95% of marker wires should be within 10 mm of the lesion in any plane

≥ 80% of operations carried out for diagnosis that prove to be benign should weigh < 20 g

≥ 95% of impalpable lesions should be correctly identified at first operation

Confirmation of identification should be made by specimen x-ray. Dedicated equipment should be available so that an x-ray can be taken of the specimen and reported to/by the surgeon within 30 minutes. Frozen sections with immediate pathological reporting at surgical biopsy should not be carried out except in exceptional circumstances. If this is the case, each occasion should be subject to audit at the quality assurance (QA) visit.

## 4. TREATMENT OF SCREEN-DETECTED BREAST CANCER

**4.1 Surgical management** Surgeons involved in the treatment of screen-detected breast cancer must be aware of all treatment options and must work to local and national NHSBSP guidelines and to those guidelines agreed by the local cancer network.

**4.2 Operative details** Women undergoing local excision for proven malignancy must have clear excision margins. It is recommended that, unless the lesion is superficial, excision should always be taken down to the deep fascia, thus ensuring clearance in a vertical plane. The excision specimen should be marked in a standard manner, in agreement with the reporting pathologist, to allow accurate orientation and assessment of resection margins. If any other than the deep margin is close or involved, re-excision should be advised to ensure complete clearance.

Increasingly, microcalcifications are the indication for surgery, and often result in underestimation of the total size of the lesion. The aim should be to obtain complete excision at the first therapeutic operation. It is recommended that only exceptionally should more than three therapeutic operations be required. This excludes any procedures carried out for breast reconstruction, which is not part of the diagnostic or ablative process.

Patients receiving surgery for screen-detected invasive breast cancer should be recommended to have axillary node staging by sampling or clearance, and this recommendation should be documented in their case notes. A minimum of four nodes should be obtained for axillary node sampling.

### Objective

To ensure complete excision following breast conserving surgery

To minimise the number of therapeutic operations

To ensure adequate pathological data to decide on appropriate adjuvant treatment

### Outcome measure

All specimens must be marked by the surgeon to allow orientation by the reporting pathologist

90% of women with single lesions (excluding multifocal tumours and those with associated extensive ductal carcinoma in situ) should not require a further operation to ensure complete excision

Patients with invasive cancers treated by surgery should have adequate axillary node assessment (minimum 90%, target 95%)

**4.3 Treatment of ductal carcinoma in situ**

The risk of local recurrence following excision of ductal carcinoma in situ (DCIS) depends not only on the extent and grade of DCIS but also, most importantly, on the adequacy of resection margins. Pending the results of clinical trials, the following factors should be considered when deciding on management of DCIS:<sup>5</sup>

- extensive mammographic lesions are unlikely to be cleared by local excision, and mastectomy with or without immediate reconstruction should be advised
- complete local excision is always advised, and in general terms the greater the excision margin the lower the risk of local recurrence<sup>6,7</sup>
- the risk of local recurrence may be reduced by postoperative adjuvant radiotherapy.<sup>8-10</sup>

Lymph node staging is not normally required in DCIS. However, for those patients in whom DCIS appears to be extensive or presents as a mammographic or palpable mass lesion, invasive cancer may co-exist, and consideration should be given to axillary staging (but not full axillary clearance).

**Quality objective**

To minimise development of local recurrence or invasive cancer following conservation surgery for DCIS

**Outcome measure**

Local recurrence less than 20% at 5 years, target 10% at 5 years

**4.4 Treatment of invasive cancer**

The risk of local recurrence following excision of invasive cancer also depends on the extent and grade of the tumour and, again importantly, on the adequacy of resection margins. Postoperative radiotherapy is also indicated for patients after conservation therapy in order to reduce the risk of local recurrence.<sup>11</sup>

## 5. FOLLOW-UP AND DATA COLLECTION

### 5.1 Data management

Any screening unit must be able to provide data on treatment and follow-up for all patients. Each screening unit must appoint a data manager and must nominate a lead surgeon to be responsible for ensuring timely collection and verification of data from individual surgeons in the screening unit's area. This should be part of the screening contract when individual surgeons undertake to treat patients with screen-detected abnormalities. Data on treatment and follow-up should be audited to the nationally agreed standard data set.

In addition, specific items for audit may be required on a regional basis for presentation at the annual meeting of the Association of Breast Surgery at BASO. These data should be discussed and approved by the surgeons within a region at their surgical QA meeting chaired by the regional surgical QA coordinator. These meetings should also be the forum for individual surgeons to discuss any difficulties that they may have in achieving the set standards. The regional coordinator has access via the breast screening QA director to bring deficiencies in the provision of care to the attention of the trust management and to apply pressure for services to improve.

Ideally, all surgeons should use the same database for recording their own information. Any information system used should capture the national minimum dataset and should be easily transferred to the audit system used nationally.

The surgeon must have the assistance of a data manager for the collection of these data. This is not just a matter of data entry but also of generating reports for regular audit purposes, which will necessitate retrieval and filing of case notes. Failure to achieve this should be reported to their screening office or through the surgical QA coordinator at the surgical QA meeting.

### 5.2 Data to be collected

Examples of a treatment and biopsy form for initial surgical data entry and a follow-up form for subsequent clinic visits are shown in Appendix 1. When completing data returns, care should be taken to adhere to the agreed surgical definitions, as laid down in Appendix 2. The national minimum cancer dataset for breast cancer may be appropriate.<sup>12</sup>

### 5.3 Generating reports

Surgeons requiring reports other than those showing standard annual statistics presented at the annual Association of Breast Surgery (ABS) at BASO meeting should request assistance from their regional QA reference centre for help on additional projects.

## 6. SURGICAL QUALITY ASSURANCE

### 6.1 Regional quality assurance

The NHSBSP quality assurance structure operates on a regional basis. The director of public health for each government office area will appoint a quality assurance director for breast screening. However, that quality assurance director and director of public health may decide to operate one or two quality assurance teams, as appropriate, depending on the population and geography of their area. A region is defined here as the area covered by a quality assurance team.

A QA director will appoint a regional surgical quality assurance coordinator. This individual has a number of responsibilities. These include:

- representing the surgical community within the regional breast screening quality assurance team
- liaising with the quality assurance director on matters of surgical quality assurance
- representing the region at the national quality assurance coordinating committee and reporting back to the surgical community within the region about activities undertaken by that committee
- convening at least one annual meeting of all the surgeons within the region involved in breast screening, at which time each surgeon should be prepared to present his or her own annual statistics in the standard format supporting individual surgeons within the region who require assistance or who are having particular difficulties
- assisting the QA director with investigation of any areas of surgical practice involving the management of patients with screen-detected abnormalities
- participating in QA visits.

### 6.2 QA visits

The statistics from each unit will be monitored at regional and national level, and units should also carry out their own audit. However, statistical review alone cannot give a sufficiently broad view of the functioning of a unit or of individual surgeons within it. The regional QA team, including the regional surgical coordinator or a surgeon from another region, will therefore visit each unit. These visits will be in accordance with a regular multidisciplinary format, as defined in *Guidelines on Quality Assurance Visits*, which was published by the NHSBSP in 2000.<sup>13</sup> It is a requirement that all units should be represented at the annual surgical meeting and that a register of attendance must be kept. A regional surgeons' subgroup meeting must be held at least annually, and all participating surgeons should present their own data. Personal discussion should take place annually between the surgical QA coordinator and the local lead surgeon to discuss surgical issues. Unit surgeons should participate if necessary. Each unit should know approximately when these discussions are to happen. This should reduce delays in implementing change and should make the triennial visit more efficient in terms of both practice and maintaining standards.

QA visits should take place at intervals of no longer than three years in parallel with the triennial programme of the NHSBSP. More frequent

visits may occur at the request of the regional QA team, at the request of the national office or because of local circumstances. The role of the regional surgical QA coordinator is vital in identifying any surgical problems that necessitate intervention earlier than the next routine visit and communicating these to the regional QA director.

Prior to the QA visit, a questionnaire must be completed and returned by the lead surgeon to the surgical QA coordinator a minimum of two weeks before the visit. These two surgeons should then discuss by telephone or in person those local issues on which particular attention should be focused during the visit. A copy of the questionnaire is included at Appendix 3.

### 6.2.1 Personnel

Each QA team is regionally based and at present has no representatives from outside the region. It is not possible for an individual surgeon to regularly be part of a team visiting other regions, although this is considered highly desirable.

It is recommended that, whenever a problem has been identified, a professional from another region shall join the regional QA team before a scheduled QA (surgical) visit or triennial visit. The professional may be any one of the clinical professionals as seems appropriate (consultant surgeon, radiologist or pathologist). The decision to invite an individual from another region will lie with the regional QA team. If serious local difficulties are identified, two professionals should be appointed to join the subsequent follow-up visit.

### 6.2.2 Case review

Case review is a requirement of the surgical component of the QA visit. The standard proforma and visit may fail to identify particular problems in surgical practice, which are only found on inspection of individual case notes. It is important that individual surgeons' practices are reviewed as well as those of the unit as a whole.

This review should include consideration of the following:

- How many times did the woman attend the assessment clinic?
- Was there a preoperative diagnosis; if so, how was it achieved? (If frozen section biopsy was carried out, a specific justification must be given.)
- What was the waiting time to surgery?
- Who performed the operation?
- Was treatment complete at the first operation?
- Was the preoperative diagnosis confirmed?
- Was axillary node staging carried out adequately for those with invasive cancer?
- Was the diagnosis and treatment discussed at MDT meetings?
- Was there an appropriate referral to oncology?
- What follow-up was arranged?

It is recommended that the surgical QA coordinator or QA reference centre randomly identifies a minimum of 10 women diagnosed with cancer. At the QA visit these patients' notes can be reviewed regarding the radiology, surgery, pathology and oncology referral from the surgical

viewpoint. Although 10 patients' notes should be reviewed per unit, there may be a variable number of surgeons in different units. Five notes for each surgeon should be reviewed. Additionally, two notes per surgeon should be reviewed for patients with benign disease.

It is recommended that the regional surgical QA coordinator takes the opportunity to visit a multidisciplinary meeting whenever possible, which should be on a day other than the official QA visit.

Surgeons should be given the opportunity to comment on the written report and correct factual inaccuracies.

### 6.2.3 *Report to the regional QA director*

It is recommended that the surgical QA coordinator returns his or her report directly to the regional QA director with clear recommendations and timescales to address deficiencies highlighted by the visit. The complete visit report will be forwarded to the regional director of public health.

### 6.3 **Achieving change**

Changes within a breast unit should be achieved by ongoing discussion and cooperation.

Where shortcomings have been clearly identified, the process described above should be adequate to achieve change. If an individual fails to recognise suboptimal practice and is unwilling to change, the responsibility lies with the regional director of public health to ensure that the NHSBSP in that unit continues to deliver a standard of care that is within guidelines and is acceptable. Individual surgeons who refuse necessary change should not continue to provide surgical care for women through the screening service.

If a unit requires a follow-up visit, this should be at an interval of no more than one year. This is because, within this timescale, problems will remain within memory as well as being on record. The extent to which local difficulties have been resolved will be discussed at each visit. It is recognised that some issues for surgeons may have cross-specialty responsibility.

It is recommended that the surgical QA coordinator provides all round support to those local surgeons whose interactions with other specialties have an impact on their own surgical practice.

## 7. ACHIEVING THE OBJECTIVES

### 7.1 At national level

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 at BASO advises the Royal Colleges on:

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

The ABS at BASO has the responsibility to:

- review the surgical results of screening programmes 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 screening units.

### 7.2 At regional level

There are two interlinked activities at the regional level:

- a QA subgroup comprising all surgeons involved with screening within a region; the regional surgical QA coordinator, appointed by the regional QA director, chairs this group
- a multidisciplinary regional QA team comprising the chairs of the individual subgroups; the regional committee is the forum for overall assessment of the programme in the region and will visit individual units to assess quality assurance (see section on surgical aspects of the QA visit). The lead surgeon for that unit should present surgical data to the committee at the time of the visit (see below).

### 7.3 At unit level

#### 7.3.1 *Audit and QA*

For each screening unit, one surgeon should be nominated as the lead surgeon 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.

The surgeon must have identified time for audit, administration and regular unit meetings to discuss case management (see 2.2). The frequency of MDT meetings depends on the population in any screening unit. It is suggested that this should equate to one meeting lasting one hour per week for each 'Forrest unit'.

It is envisaged that each unit will have a data manager to facilitate retrieval of notes, to ensure timely completion of biopsy and treatment forms by

surgeons and to oversee data entry and data retrieval. The provision of staff and availability of time for these activities should be part of the screening contract and should be the responsibility of management.

### 7.3.2 *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. Surgeons involved in screening should have attended an approved multidisciplinary training course.

### 7.3.3 *Clinical trials*

Surgeons are encouraged to offer all eligible women an appropriate trial or study.

### 7.3.4 *Surgeons' time*

This very much depends on the number of surgeons accepting patients with screen-detected abnormalities for treatment from any one screening unit. However, it is estimated that at least one operating session per week will be required for cases arising from one 'Forrest unit'.<sup>14,15</sup> This will comprise treatment of patients diagnosed with breast cancer and also treatment of those patients requiring diagnostic marker biopsies with reoperation to clear margins and to treat the axilla if necessary. Depending on the working arrangements for assessment sessions (see above), sessional time is also required for surgeons to see patients and to attend multidisciplinary meetings.

### 7.3.5 *Data management*

Data entry should be complete, accurate and timely, which requires a properly trained and remunerated data manager. The data manager is an essential component of the core breast unit team. This member of the core breast unit team will interact closely with the symptomatic practice, and at least one full time data manager is required for each breast unit.

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**APPENDIX 1: EXAMPLES OF A BIOPSY  
AND TREATMENT FORM AND A  
FOLLOW-UP DETAILS FORM**

NHS Number:

Surname:

Forenames:

Title:

Date of birth:

Date of diagnosis:

---

**FOLLOW-UP DETAILS**

Hospital:

Hospital No:

Consultant:

Surgeon:

Radiotherapist:

---

**Biopsy**

Date:

Location:

Side:

Lesion No:

Diagnosis by cytology alone? 

Site:

Entered into national trial (Y/N)?

Which trial:

**Biopsy procedure** Wide bore needle biopsy Localisation ultrasound Excision biopsy palpable Excision biopsy impalpable, localisation x-ray Excision biopsy impalpable**Additional biopsy procedures** Guidance by ultrasound Frozen section – benign Guidance by x-ray Frozen section – diagnosis deferred Frozen section – malignantBiopsy result  Normal Benign Malignant**Treatment procedure**

Date:

 No treatment Subcutaneous mastectomy Initial biopsy was treatment Subcutaneous mastectomy/immediate implant Wide local excision (WLE) Simple mastectomy Repeat WLE to clear margins Patey (modified radical mastectomy) Segmentectomy or quadrantectomy Radical mastectomy Other**Additional treatment procedures** No additional treatment procedures Internal mammary node sampling No lymph node procedures Other nodes biopsied Axillary node sampling Radiotherapy  Breast  Lymph Sentinel node biopsy Lymph nodes Axillary clearance – level 1 Chemotherapy Axillary clearance – level 2 Endocrine Axillary clearance – total Guidance by ultrasound Guidance by x-ray**Follow-up visit (weeks)**

Procedure:

Comment:

**BSS: FOLLOW-UP DETAILS FORM**

Sx Number:

Name:

NHS Number:

Surname:

Forenames:

Title:

Date of birth:

Date of diagnosis:

**FOLLOW-UP DETAILS**

Hospital:

Hospital No:

Consultant:

Surgeon:

Radiotherapist:

Treatment surgery:

Side:

Treatment radiotherapy:

Treatment systemic:

Lesion No:

Current trial code:

Date of follow-up:

Complication of Rx?

Surgery:

Radiotherapy:

Chemotherapy:

**Current status** 1. Disease free 2. New recurrence this side Local Regional Metastatic Confirmed Confirmed Confirmed

New/change of treatment

 Local surgery Salvage mastectomy Ablative surgery Systemic hormone therapy Systemic chemotherapy Radiotherapy 3. New disease other side 4. Previously diagnosed Local Regional Metastatic 5. Non-attendance D or A BCa main cause

Date:

BCa contributory cause

Further details:

Next appointment (weeks):

Clinician:

Appointment type

 Routine FU Radiotherapy Oncology

Comments:

## APPENDIX 2: SURGICAL DEFINITIONS

## Quality Assurance Guidelines for Surgeons in Breast Cancer Screening

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<b>Term</b>	<b>Reference</b>
Cancer	Although it is highly desirable that a positive cytological or histological diagnosis of primary breast malignancy should be obtained, women with cancers diagnosed in the screening programme on radiological and/or clinical grounds alone should be included as women with cancer. In this situation, the best available information about tumour size should be used but no attempt should be made to classify the tumour type (ie into invasive or non-invasive). See LCIS and Malignancy below.
Malignancy	For the purposes of breast screening, malignant tumours strictly should include only primary breast carcinomas. Ideally, other malignant tumours diagnosed as a result of screening, such as lymphoma in an axillary lymph node or secondary melanoma in the breast, should not be included in measures of the effectiveness of the screening programme, ie counts of cancers detected and malignant–benign ratios. Reports for the QA Surgical Summary (QASS) breaking down the types of malignant tumours found by the screening programme should separately identify such tumours.
Invasive cancer	When the term ‘invasive cancer’ is specified rather than just ‘cancer’ or ‘malignant tumour’, it should refer only to primary breast carcinomas with a histological diagnosis.
Lobular carcinoma in situ (LCIS)	LCIS is included as a cancer nationally but should be separately identified when breaking down cancer types. (Views are divided on its true place as a cancer, but the current national decision to include LCIS as a cancer will be respected.)
Paget’s disease	Paget’s disease should be included with DCIS only if no invasive cancer is also present.
Local recurrence	Recurrence in ipsilateral breast or mastectomy flaps.
Regional recurrence	Recurrence in regional lymph nodes, ie internal mammary, axillary and/or infraclavicular nodes.
Metastases (preferred term is distant metastases)	Spread of disease beyond locoregional sites.
Biopsy	The term ‘biopsy’ should not be used alone but should be qualified by one of the following biopsy types: fine needle aspiration cytology (FNAC), wide bore needle (WBN) or open biopsy plus localisation.
Fine needle aspiration cytology (FNAC)	Cells obtained for cytological examination and including cytology nipple discharge and scrape cytology of nipple.
Wide bore needle (WBN)	Tissue obtained for histological examination by percutaneous needle or drill biopsy.
Open biopsy	Formal operative excision of tissue for histological examination (excluding wide bore needle biopsy). The term ‘surgical biopsy’ should be replaced by ‘open biopsy’.

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Open biopsy with localisation	<p>Open biopsy for an impalpable lesion, the position of which has been marked by a radiologist (synonym: localisation biopsy or marker biopsy).</p> <p>The term should be used when there is no clear preoperative diagnosis that cancer or carcinoma in situ is present.</p> <p>A therapeutic excision of a cancer or area of carcinoma in situ may be carried out with localisation. In this procedure a wide excision is the intended operation. This should not be termed 'biopsy'.</p>
Date of diagnosis	<p>In order of priority:</p> <p>Date that malignant FNAC (C5) taken</p> <p>If not C5, date of malignant histology (HM) sample taken if available</p> <p>If R5 and P5 (radiology and clinical examination, but no cytology or histology), date of clinical examination</p> <p>If R5 and no clinical examination, date of screening</p> <p>If P5 but no R5 (clinical examination but no cytology or histology), date of clinical examination. NB: This is strongly discouraged by the screening programme.</p>
Order of severity of breast carcinomas (needed to identify worst case when bilateral or multiple tumours)	<p>Nodes (and number positive), tumour type, vascular invasion and size should be considered. However, the following pragmatic prioritisation will serve the purpose for the small number of occasions when it may be needed, although it may not be 100% precise for prognosis.</p> <p>Node positivity (+ or -) &gt; <i>significant</i> &gt; <b>tumour type</b> &gt; <i>significant</i> &gt; tumour size.</p> <p>Thus, node + will select side to use if bilateral cancer and only one side is N+. For multiple tumours in one breast or both breasts when node status equal, tumour type should be selected according to the ordering shown below. Size should be considered only to select most significant tumour when more than one of same type.</p> <p>Tumour type order:</p> <p>Invasives:</p> <p>IDC grade 3</p> <p>IDC grade 2</p> <p>ILC</p> <p>Medullary</p> <p>IDC grade 1</p> <p>Other special types (as defined in surgical QA guidelines)</p> <p>Microinvasive – definite</p> <p>Non-invasives:</p> <p>Microinvasive – probable</p> <p>DCIS</p> <p>LCIS</p>
Malignant–benign ratio	<p>As per Pritchard (1993), refers only to open biopsies, which is a change from previous definitions. It should exclude those women from whom a benign lesion is removed only at the woman's request after a return to routine recall decision.</p>
Open biopsy with localisation with benign outcome	<p>Use heaviest if more than one biopsy in one breast or bilateral.</p>

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Tumour size	Histological size of invasive or non-invasive cancer is used where available. When no histology is available, the best available size from mammography, ultrasound or clinical examination (in order of preference) should be used. NB: It should be known that microinvasive carcinomas have recently been redefined so that those with possible microinvasion are actually included within the DCIS group (and hence will take the size of the DCIS) and those with definite microinvasion are included in the invasive < 10 mm group (the size of the invasive lesion will be less than or equal to 1 mm, by definition). The KC62 definitions include 10 to < 15 mm and 15 to < 20 mm groupings, and those should now be used in the QASS summary information and detailed breakdown of invasive tumours. This will allow the outcome measures of the 'percentage of patients having breast conservation for invasive tumours < 15 mm' to be determined.
Number of women with cancer ≤ 15 mm	This item appears in the summary information of the QASS report. Change definition to 'number of women with invasive cancer < 15 mm'. Thus, those with no histology or no size on histology will not be included, conforming with the definition of 'invasive cancer' above.
Number of women with cancers of special type	This item appears in the summary of information of the QASS report. Change definition to 'number of women with invasive cancer of special type'. Thus, those with no histology or no size on histology will not be included, conforming with the definition of 'invasive cancer' above.
Percentage of cancers with preoperative tissue diagnosis	This item appears in the summary information of the QASS report, including all women with a C5 FNAC or malignant B5 WBN where no open biopsy procedure is present.
Biopsy table in QASS	<p>The original draft QASS report published in the surgical QA guidelines showed the benign and malignant outcomes of FNACs and surgical biopsies. The table should be amended to give columns for FNAC, WBN and open biopsy. Rows should be shown only for malignant diagnosis and for the total number of biopsies performed in each column. An individual woman should therefore appear in only one column, which was the most significant diagnostic method for her. The order of significance should be determined as follows</p> <p>open biopsy if present WBN if present and malignant FNAC if present</p> <p>This is necessary to avoid the reporting of FNACs with a C4 or C3 result as benign or malignant. It will also not identify the total number of biopsies in each column if a woman has more than one type of biopsy. A separate breakdown of actual FNAC results should be optionally available to identify false positives particularly.</p>
Histological node status for invasive tumours	This can be identified from the table of invasive cancers.
Management of DCIS	This can be identified from the table of in situ cancers.
Trial entry	This can be identified from the tables of invasive and in situ cancers.

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A number of objectives are identified within the surgical QA guidelines but are not currently being monitored.

The following objectives have been specified to assist surgeons who may be having local difficulties with hospital facilities. Under such circumstances, it is envisaged that short term collection of the necessary data to monitor the relevant outcome measures would be instigated but that routine collection of such data nationally would not be necessary.

<b>Term</b>	<b>Reference</b>
Position of marker wires	Measure the maximum distance that the wire passes by the edge of the mammographic abnormality.
Specimen x-ray time	The time between the end of the excision procedure and receipt of the specimen x-ray or report in the theatre.

The following objectives should be evaluated as part of the QASS report although they are not currently included.

<b>Term</b>	<b>Reference</b>
Excision of mammographic abnormality at first biopsy	This is very difficult to identify accurately from the data which are currently recorded. Although the BT histopathology form records whether the mammographic abnormality is present in the specimen, this may be the opinion of the pathologist only rather than that of a multidisciplinary review. Additional data items which might be looked at are the number of open biopsies for one side of a woman and a diagnostic BT problem may arise if a repeat biopsy was carried out in a subsequent time period. It is hoped that the number of biopsies in this group will be very small and they should therefore be listed as part of the exception report for manual scrutiny.
Number of repeat therapeutic procedures	If WLE is recorded as a diagnostic procedure, it should be counted as a first treatment procedure and added to the count of treatment procedures. A problem may arise if a repeat treatment procedure is carried out in a subsequent time period.
Adequacy of node sampling	The guidelines state (p. 6) that a minimum of four lymph nodes should be obtained for adequate sampling. Can be identified from the histology records of patients having additional treatment procedures or axillary node sampling.
Completeness of excision in breast conservation	Can be identified from the histology record.

### APPENDIX 3: QA VISIT QUESTIONNAIRE

Name of unit visited \_\_\_\_\_ Name of surgeon \_\_\_\_\_

Name of visitor \_\_\_\_\_ Date \_\_\_\_\_

1. Names of surgeons involved in the management of breast disease at this unit:

a) name of surgeon(s) and number of contractual sessions for symptomatic surgeons

i) \_\_\_\_\_

ii) \_\_\_\_\_

iii) \_\_\_\_\_

b) name of surgeon(s) and number of contractual sessions for screening surgeons

i) \_\_\_\_\_

ii) \_\_\_\_\_

iii) \_\_\_\_\_

2. Name of lead surgeon.

\_\_\_\_\_

3. What arrangements are there to cover consultant absence, leave, etc?

\_\_\_\_\_

\_\_\_\_\_

4. Do you have dedicated assessment clinics? If 'yes', how often are they held?

\_\_\_\_\_

\_\_\_\_\_

5. Does assessment by one of the surgeons named at 1(b) take place at the first visit for assessment? If 'no', please explain the preoperative visits made by a patient before surgery.

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

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6. Are you satisfied with the facilities and working arrangements for assessment?

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7. a) Do you have a breast care nurse with appropriate experience, education, skills and training?

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b) Does the nurse meet current nursing PREP requirements?

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c) If you do not have a breast care nurse, what arrangements exist for supporting patients?

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8. Is there a room available with sufficient privacy to discuss diagnosis and treatment with patients?

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9. How long does it take to report cytology or core biopsy?

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10. Are you satisfied with the service you receive?

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11. Please provide the following data for each surgeon in your unit. Is the performance demonstrated by these statistics satisfactory?

a) number of cancers managed annually

i) symptomatic \_\_\_\_\_

ii) screen detected \_\_\_\_\_

b) average waiting time between assessment and first surgical procedure

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c) average waiting time between diagnosis and first major therapeutic intervention

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- d) percentage of patients with a preoperative diagnosis  
\_\_\_\_\_
- e) treatment of DCIS
- i) no of cases \_\_\_\_\_
  - ii) no and % simple mastectomies \_\_\_\_\_
  - iii) no and % WLEs \_\_\_\_\_
  - iv) no and % other \_\_\_\_\_
- f) treatment of invasive cancers
- i) no of cases \_\_\_\_\_
  - ii) no and % mastectomies \_\_\_\_\_
  - iii) no and % mastectomy plus axillary clearance/sampling \_\_\_\_\_
  - iv) no and % WLEs \_\_\_\_\_
  - v) no and % WLE plus axillary clearance/sampling \_\_\_\_\_
- g) number and % of patients undergoing breast reconstruction  
\_\_\_\_\_
- h) number of operations per patient for treatment
- i) no and % of patients having one operation \_\_\_\_\_
  - ii) no and % of patients having two operations \_\_\_\_\_
  - iii) no and % of patients having three or more operations \_\_\_\_\_
  - iv) outcome of patients surgically treated for screen-detected breast cancer
  - v) total no of screen-detected cancers \_\_\_\_\_
  - vi) no of patients disease free (at specified date) \_\_\_\_\_
  - vii) no of patients with recurrent diseases (at specified date) \_\_\_\_\_
  - viii) no of patients died (before specified date) \_\_\_\_\_

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12. Are multidisciplinary meetings held with radiologists, pathologists and radiotherapists/oncologists? Yes/No

If not, why?

\_\_\_\_\_

- a) How often are they held?

\_\_\_\_\_

- b) Are preoperative patients discussed?

\_\_\_\_\_

- c) Are you satisfied in the way these multidisciplinary meetings are run and attended?

\_\_\_\_\_

- d) Who keeps a record of these multidisciplinary meetings?

\_\_\_\_\_

13. Do you have any problems with collection and retrieval of surgical data? Do you have a computerised system?

\_\_\_\_\_

\_\_\_\_\_

14. Do you follow up women with screen-detected cancers? How often is this carried out?

\_\_\_\_\_

\_\_\_\_\_

15. Who is responsible for providing follow-up data to the breast screening unit and QA reference centre?

\_\_\_\_\_

\_\_\_\_\_

16. For which breast cancer trial(s) does this unit have ethical committee approval?

\_\_\_\_\_

- a) How many patients have been entered into the trial(s) mentioned above in the last year?

\_\_\_\_\_

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b) Are there any problems with trial entry?

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17. In what way have you ensured your continuing medical education in breast cancer in the last year (eg meetings, courses, etc).

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18. Do you have difficulty in obtaining either study leave or financial support from your employers for CME?

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19. Are there any specific meetings or training packages you have attended over the last year which you would recommend to others?

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20. What do you believe are the strengths of this unit?

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21. Are there any other comments you would wish to make?

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