

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

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CONTENTS

	Page No
1 INTRODUCTION	1
2 ASSESSMENT	2
2.1 Assessment clinics	2
2.2 Multidisciplinary meetings	3
2.3 Surgeons' screening caseload	3
3 DIAGNOSIS	4
3.1 Non-operative biopsy	4
3.2 Operative biopsy	5
4 TREATMENT OF SCREEN-DETECTED BREAST CANCER	7
5 SURGICAL QUALITY ASSURANCE	14
5.1 Surgical aspects of NHSBSP quality assurance in the strategic health authority	14
5.2 Surgical aspects of NHSBSP quality assurance in the breast screening unit	15
5.3 Assessment of surgical performance in the breast screening programme	17
6 ACHIEVING THE OBJECTIVES AS A NATIONAL PROGRAMME	19
6.1 Professional liaison	19
6.2 Clinical trials and prospective studies	19
REFERENCES	20
APPENDIX 1: NBSS SURGERY FORM	21
APPENDIX 2: NOTES ON COMPLETION OF THE CLINICAL RECORD ON NBSS	24
APPENDIX 3: NHSBSP NATIONAL COORDINATION GROUP FOR SURGEONS IN BREAST SCREENING	29

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1 INTRODUCTION

The NHS Breast Screening Programme (NHSBSP) has been a quality assured programme from the outset. It always endeavours, through its quality assurance (QA) initiatives, to ensure that women receive the same high standards of care, and ultimately of diagnosis, wherever they live, and that the standards are constantly improving. The first QA guidelines for surgeons working with the NHSBSP were produced in 1992 by the Breast Surgeons Group at BASO (now the Association of Breast Surgery (ABS) at BASO).¹ This group compiled the guidelines and the publication outlined preferred practice at that time for the diagnosis and management of women with screen-detected breast cancer. These QA guidelines were updated in 1996 and again in 2001 and have now been extensively rewritten for the current edition.² As with previous publications, this publication is part of the screening programme's overall QA initiative and aims 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 other NHS initiatives and in particular the NHS Cancer Programme and the Cancer Reform Strategy.^{3,4}

Ultimately, the screening process can be successful only if it is followed by timely and appropriate management of the detected breast cancers by surgeons and their colleagues within the multidisciplinary team (MDT). The QA objectives and targets within this document are those that directly involve surgeons. However, the surgeon is a key member of the multidisciplinary team, and these guidelines fit within the overall process as the surgeon fits within that overall team.

The management of breast cancer from the point of diagnosis 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 on issues specific to the NHSBSP. They should be used in conjunction with *Surgical Guidelines for the Management of Breast Cancer* which are being published simultaneously.⁵ The quality standards published in that document are listed in Chapter 4 of this publication.

The guidelines are addressed principally to surgeons working in the screening programme, who will use them in a personal capacity to audit their own activity. They will assist the regional QA 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 to ensure that women with screen-detected breast cancer are cared for in an optimal manner.

2 ASSESSMENT

2.1 Assessment clinics

NHSBSP standards relevant to assessment and surgery are shown in Table 1. Most screen-detected abnormalities are impalpable; therefore, the assessment process is usually directed by radiologists or breast physicians. Results of needle biopsies taken at assessment clinics must be discussed at the weekly MDT meeting before the results are discussed with the woman (see section 2.2).

For women who are diagnosed non-operatively, the time interval between non-operative biopsy and the result being given to the patient should be one week or less. Needle biopsy results should be discussed with the woman in the presence of a breast care clinical nurse specialist. Ideally, a surgeon should also attend the assessment clinic in order to minimise clinic visits by the woman. However, it is recognised that, in many units, screening assessment clinics are staffed solely by radiologists, specialist radiographers and breast clinicians. If not seen by a surgeon at the assessment clinic, those women who require a surgical opinion should be reviewed by the surgeon within one week. The surgical clinic appointment should be arranged and given to the woman before she leaves the assessment clinic. Local guidelines should be agreed to ensure that there are no undue delays between radiological and surgical assessment.

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. The NHS Cancer Plan⁶ sets 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. The maximum two month (62 day) wait from urgent GP referral to first treatment for all cancers has not previously applied to screening patients as there is no GP referral for screening patients. However, in accordance with the Cancer Reform Strategy, published in December 2007, screening patients were formally brought into this target from December 2008.⁴ Separate guidance is in preparation to assist in determining how the 62 day target will be applied in the screening programme.⁷ 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. The two week NHSBSP waiting time target for diagnostic open surgical biopsy has again been included in these guidelines (see Table 1). 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. For patients having surgical removal of a pathologically proven benign lesion (ie not diagnostic) the 18 week target waiting time will apply.

Table 1 NHSBSP waiting time targets relevant to assessment and surgery

Objective	Criterion	Minimum standard	Target
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%
To minimise the interval from the decision that diagnostic surgery is required to the date of diagnostic surgery	Proportion of women who are admitted within two weeks of assessment for surgery for diagnostic purposes	≥90%	100%

2.2 Multidisciplinary meetings

Attendance at the MDT meeting is critical for all involved. This is an essential 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 where a needle biopsy has been carried out and those in which return to routine screening is not the obvious outcome. Further guidance is given in *Clinical Guidelines for Breast Cancer Screening Assessment*.⁸

A record of those who attend MDT meetings and the minutes of those meetings, including the actions agreed, must be retained by each screening unit. The record of attendances and the minutes of the meetings should be available for inspection at any QA 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 his or her representative before treatment options are discussed with the patient.

2.3 Surgeon screening caseload

Each surgeon involved in the NHSBSP 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. Surgeons with particularly low or very high annual caseloads may be subject to particular scrutiny to ensure that all outcome measures meet national QA standards.

3 DIAGNOSIS

3.1 Non-operative biopsy

A non-operative 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 assessed as borderline on the basis of imaging and needle biopsy. Women with an initial indeterminate core biopsy or cytology result should be considered for further biopsy (core or vacuum assisted) before proceeding to operative biopsy (also described as open surgical biopsy). This consideration should be discussed by the MDT and is particularly important for women with an initial B4 result.

Compared with 10 years ago, when the non-operative diagnosis rate was only 66%, figures from the recent annual NHSBSP/ABS at BASO audits of screen-detected cancers indicate that a non-operative diagnosis is achieved on average in over 90% of cases.^{9,10} It is recognised that invasive cancers have a higher non-operative diagnosis rate, and in the 2006/7 audit 98% of invasive cases were diagnosed non-operatively.¹⁰ In situ cases are more difficult to diagnose, but 81% were diagnosed without open biopsy in the last ABS at BASO audit.¹⁰

The standards for non-operative diagnosis are given in Table 2.

Although every effort must be made to establish a non-operative diagnosis, excessive delay by repeated attempts at diagnosis by needle biopsy should be avoided. It is recommended that needle biopsy should be performed on a maximum of two occasions on the same breast lesion. Additional procedures may be required if multifocal disease is suspected or to assess suspected axillary lymph node involvement. If a diagnosis is still not established, open surgical biopsy should be performed.

Table 2 NHSBSP standards for non-operative diagnosis

Objective	Criterion	
	Minimum standard	Target
To minimise unnecessary surgery, and diagnostic open surgical biopsies that prove to be malignant	90% of all <i>invasive</i> cancers should have a non-operative pathological diagnosis 85% of all <i>non-invasive</i> cancers should have a non-operative pathological diagnosis	95% of all <i>invasive</i> cancers should have a non-operative pathological diagnosis 90% of all <i>non-invasive</i> cancers should have a non-operative pathological diagnosis
To minimise benign diagnostic open surgical biopsies	<15 per 10 000 women <i>prevalent</i> screen <10 per 10 000 women <i>incident</i> screen	<10 per 10 000 women <i>prevalent</i> screen <7.5 per 10 000 women <i>incident</i> screen

3.2 Operative biopsy

Operative 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. 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.

3.2.1 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.

3.2.2 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 MDT meeting. If the radiologist reports the film at once, no more than 20 minutes should elapse before the reported film is received by the operating surgeon.

3.2.3 Frozen section pathology

Frozen sections with immediate pathological reporting at open surgical 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 subject to audit at the QA visit.

3.2.4 Weight of biopsy specimens

The fresh weight of tissue removed for all cases in which a diagnostic open surgical 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 MDT meeting and any mitigating reasons recorded. All such cases should also be scrutinised at the next QA visit.

3.2.5 NHSBSP standards

The NHSBSP standards for open surgical biopsy are given in Table 3.

Table 3 Standards for open surgical biopsy

Objective	Outcome measure
To maximise the identification of mammography-detected lesions	> 95% of marker wires should be within 10 mm of the lesion in any plane
To minimise the cosmetic impairment of diagnostic open surgical biopsy	The fresh weight of tissue removed for all cases in which a diagnostic open surgical biopsy is performed should be recorded ≥90% of open surgical biopsies carried out for diagnosis which prove to be benign should weigh ≤20 g All cases in which diagnostic open surgical biopsies prove to be benign and weigh >40 g should be discussed at the post-operative MDT meeting and any mitigating reasons recorded. These cases should all be discussed at the next QA visit
To ensure the diagnostic accuracy of open surgical biopsy	≥98% of impalpable lesions should be correctly identified at the first operation

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4 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 ductal carcinoma in situ (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 for the Management of Breast Cancer* which have been published simultaneously with this document.⁵ The quality objectives and outcome measures relevant to breast cancer screening surgeons that are published in those guidelines are listed below:

Multidisciplinary team meetings

Quality objectives	Outcome measures
An MDT meeting should take place to discuss patient management, before treatment options are discussed with the patient	An MDT meeting should take place weekly. A record of the meeting, including the attendance, should be kept
Adequate resources should be provided to support a functioning MDT meeting	Each MDT should have a MDT co-ordinator. The MDT meeting should be a fixed clinical commitment

Treatment planning

Quality objectives	Outcome measures
Breast cancer treatment should be provided in a consistent manner according to agreed local guidelines	Each breast unit must have written guidelines for the management of breast cancer
The management of patients with breast cancer should be discussed by an MDT	The management of all patients with newly diagnosed breast cancer should be discussed at an MDT meeting and the conclusions documented in each patient's notes

Quality Assurance Guidelines for Surgeons in Breast Cancer Screening

Organisation of surgical services

Quality objectives	Outcome measures
To ensure specialist surgical care	Breast cancer surgery should be performed only by surgeons with a specialist interest in breast disease (defined as at least 30 surgically treated cases per annum)
To minimise patient anxiety between a decision that a diagnostic operation is required to confirm or exclude malignancy and the date for an operation	Patients should be admitted for a diagnostic operation within two weeks Minimum standard: $\geq 90\%$ within two weeks Target: 100% within two weeks
To minimise patient anxiety between a decision that a therapeutic operation is required for cancer and the date for operation	100% of patients should receive their first treatment within 31 days of the 'decision to treat'. If surgery is the primary treatment, then patients should be offered a date for surgery within 31 days of the 'decision to treat' Target: 100% admitted for operation within 31 days, if surgery is the first treatment
To minimise the delay between referral for investigation and first breast cancer treatment	100% of patients diagnosed with breast cancer should receive their first treatment within 62 days of an urgent GP referral with suspected breast cancer or recall from the NHSBSP. If surgery is the primary treatment, then patients should be offered a date for surgery within 62 days of the date of referral Target: 100% admitted for operation within 62 days, if surgery is the first treatment
To minimise unnecessary investigations prior to breast cancer treatment	Non-operative staging investigations for metastatic disease should not be routinely performed

Surgery for invasive breast cancer

Quality objectives	Outcome measures
Patients should be fully informed of the surgical treatment options available to them	When appropriate, patients should be given an informed choice between breast conservation surgery and mastectomy. If a choice of breast conservation surgery is not offered, the reasons should be documented in the patient's case notes
Patients should have access to breast reconstruction surgery	All patients having treatment by mastectomy (by choice or on advice) should have the opportunity to discuss their breast reconstruction options and have immediate breast reconstruction if appropriate. If breast reconstruction is not offered, the reasons should be documented in the patient's case notes
To ensure adequate assessment of surgical excision of an invasive cancer treated by breast conservation surgery	Intraoperative specimen radiography should be carried out for all cases requiring radiological localisation and is recommended for all wide local excision specimens All specimens must be marked by the surgeon according to local protocols to allow orientation by the reporting pathologist
To ensure adequate surgical excision of an invasive cancer treated by breast conservation surgery	All patients should have their tumours removed with no evidence of disease at the microscopic radial margins and fulfilling the requirements of local guidelines If, after MDT meeting discussion, the margin of excision is deemed to be inadequate, then further surgery to obtain clear margins should be recommended
To minimise the number of therapeutic operations in women undergoing conservation surgery for an invasive cancer	Minimum standard: >95% of patients should have three or fewer operations Target: 100% of patients should have three or fewer operations
To minimise local recurrence after breast conservation surgery for invasive malignancy	Minimum standard: <5% of patients treated by breast conservation surgery should develop local recurrence within five years Target: <3% of patients treated by breast conservation surgery should develop local recurrence within five years
To minimise local recurrence after mastectomy for invasive malignancy	Minimum standard: <5% of patients treated by mastectomy should develop local recurrence within five years Target: <3% of patients treated by mastectomy should develop local recurrence within five years

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Axillary node management in invasive breast cancer

Quality objectives	Outcome measures
To increase the non-operative diagnosis of axillary node metastases	Target: all patients diagnosed with invasive breast cancer undergoing surgical treatment should have a preoperative axillary ultrasound scan, and if appropriate fine needle aspiration (FNA) or core biopsy should be carried out
To ensure adequate surgical treatment of involved axillary lymph nodes	<p>If a positive non-operative diagnosis of axillary node metastasis is made in a patient undergoing surgery for breast cancer, the patient should normally proceed to axillary clearance</p> <p>Patients with positive (macrometastases or micrometastases) axillary staging procedures should proceed to subsequent treatment for axillary disease. This may take the form of complete (ie full) axillary clearance, axillary radiotherapy or entry into an appropriate clinical trial. This should be discussed at the MDT meeting according to local guidelines and the reasons should be documented in the patient's case notes</p> <p>When axillary node clearance is carried out, the level of anatomical dissection should be specified, and at least 10 nodes should be retrieved</p> <p>Minimum standard: >90%</p> <p>Target: 100%</p>
To ensure adequate staging of the axilla in patients with invasive breast cancer	<p>Patients treated surgically for early invasive breast cancer should have an axillary staging procedure carried out if metastatic nodal metastasis is not confirmed non-operatively</p> <p>Minimum standard: >90%</p> <p>Target: 100%</p> <p>When axillary node sampling is carried out, at least four nodes should be retrieved</p> <p>Minimum standard: >90%</p> <p>Target: 100%</p>
To minimise morbidity from axillary surgery to obtain staging information	Sentinel node biopsy using the combined blue dye/ radioisotope technique is a recommended axillary staging procedure for the majority of patients with early invasive breast cancer
Axillary recurrence should be minimised by effective staging and treatment where appropriate	<p>Minimum standard: <5% axillary recurrence at five years</p> <p>Target: <3% axillary recurrence at five years</p>

Surgery for ductal carcinoma in situ

Quality objectives	Outcome measures
Patients with DCIS should be fully informed of the surgical treatment options available to them	When appropriate, patients should be given an informed choice between breast conservation surgery and mastectomy. This includes the difference in local recurrence rates between the two approaches. If a choice of breast conservation surgery is not offered the reasons should be documented in the patient's case notes
Patients with DCIS should have access to breast reconstruction surgery	All patients having treatment by mastectomy (by choice or on advice) should have the opportunity to discuss their breast reconstruction options and have immediate breast reconstruction if appropriate. If breast reconstruction is not offered, the reasons should be documented in the patient's case notes
To ensure adequate assessment of surgical excision of DCIS treated by breast conservation surgery	Intraoperative specimen radiography should be carried out for all cases of DCIS treated by breast conservation surgery All specimens must be marked by the surgeon according to local protocols to allow orientation by the reporting pathologist
To ensure adequate surgical excision of DCIS treated by breast conservation surgery	All patients should have their tumours removed with no evidence of disease at the microscopic radial margins and fulfilling the requirements of local guidelines If, after MDT meeting discussion, the margin of excision is deemed to be inadequate then further surgery to obtain clear margins should be recommended
To minimise the number of therapeutic operations in women undergoing conservation surgery for DCIS	Minimum standard: >95% of patients should have three or fewer operations Target: 100% of patients should have three or fewer operations
To minimise local recurrence after breast conservation surgery for DCIS	Patients with extensive (>40 mm diameter) or multicentric disease should usually undergo treatment by mastectomy
To minimise morbidity from axillary surgery	Axillary staging surgery is not routinely recommended for patients having treatment for DCIS alone. It may be considered in patients considered to be at high risk of occult invasive disease. The decision to carry out an axillary staging procedure should be discussed at the preoperative MDT meeting and recorded in the patient's case notes. Axillary node clearance is contraindicated in patients with DCIS alone
To minimise local recurrence after breast conservation surgery for DCIS	Target: < 10% of patients treated by breast conservation surgery should develop local recurrence within five years
To increase understanding of the diagnosis and treatment of DCIS	All breast screening units should participate in the national audit of the management of non-invasive breast cancer, the Sloane Project

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Breast reconstruction

Quality objectives	Outcome measures
Patients should have access to breast reconstruction surgery	All patients having treatment by mastectomy (by choice or on advice) should have the opportunity to discuss their breast reconstruction options and have immediate breast reconstruction if appropriate. If breast reconstruction is not offered the reasons should be documented in the patient's case notes.
Patients not undergoing immediate breast reconstruction should be provided with breast prostheses	Breast units should have surgeons with oncoplastic experience and/or have the rapid availability of a plastic surgeon. Adequate time for consultation and surgery must be available Breast prostheses should be freely available to patients treated by mastectomy together with easy access to a fitting service

Peri- and post-operative care

Quality objectives	Outcome measures
To ensure that breast cancer patients receive adequate support and treatment throughout their care	All patients treated for breast cancer should be supported by a breast care nurse or clinical nurse specialist throughout their care. Adequate information about follow up and support groups should be made available
To ensure adequacy of surgical treatment and plan adjuvant treatments	All patients should be discussed at the 'post-operative results' MDT meeting and a plan for any further treatment and follow up documented in the case notes

Adjuvant treatments

Quality objectives	Outcome measures
To ensure the adequacy of surgical treatment and to plan adjuvant treatments	All patients should be discussed at the 'post-operative results' MDT meeting and a plan for any further treatment and follow up documented in the case notes Written local breast cancer treatment guidelines should identify which patients should be considered for adjuvant treatments (radiotherapy, endocrine therapy, chemotherapy and targeted therapies)
To ensure that all patients have access to appropriate adjuvant treatments	The ER and HER2 status should be determined in every case of invasive breast cancer, with the results available for the 'post-operative results' MDT meeting

Clinical follow up

Quality objectives	Outcome measures
To ensure appropriate clinical follow up of breast cancer patients	Each breast unit should have agreed local guidelines for clinical follow up of patients with breast cancer (including mammographic surveillance) and mechanisms for the rapid re-referral of patients with suspected recurrence
To ensure adequate collection of outcome data on all patients treated for breast cancer	Appropriate data management resources should be available to record follow up and outcome data
To ensure breast unit participation in national audits	All breast units should participate in ongoing national audits such as the NHSBSP audits, the Breast Cancer Clinical Outcomes Measures (BCCOM) audit and the Sloane Project

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5 SURGICAL QUALITY ASSURANCE

5.1 Surgical aspects of NHSBSP quality assurance in the strategic health authority

The NHSBSP is a quality assured programme. This runs through all aspects of the screening programme, including the surgeon's role in the diagnosis and treatment of screen-detected cancers. In order to deliver QA, an infrastructure was established in the early years of the programme that has been adapted as the NHS has evolved, but which has shown increasing strength. It has contributed to improving the standard of care offered to women who enter the breast screening programme.

5.1.1 QA roles

The Regional Director of Public Health for each strategic health authority (SHA) appoints a QA director for breast screening. The QA director brings together a multidisciplinary QA team including a lead surgeon as the QA coordinator for surgical aspects of breast screening quality assurance.

5.1.2 Lead surgeon for QA

The lead surgeon appointed as the SHA surgical QA coordinator has a number of responsibilities. These include:

- representing the surgical community within the regional breast screening quality assurance team
- liaising with the QA director on matters of surgical quality assurance
- representing the SHA at the national QA coordinating group for surgeons in breast cancer screening and reporting back to the surgical community in the region about activities undertaken by that group
- supporting individual surgeons in 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
- convening at least one annual meeting of all the surgeons in 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 (see section 5.1.4)
- participating in regular QA visits in which he or she leads the surgical aspects (see section 5.3.3).

5.1.3 Regional QA groups

There are two interlinked groups at an SHA level which involve surgeons:

- a surgeons' QA group comprising all surgeons involved with screening in the region; the lead surgical QA coordinator, appointed by the QA director, 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 chairs 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 (see section 5.3.3 on surgical aspects of the QA visit). The lead surgeon for each unit visited should present surgical data at the time of the visit.

5.2 Surgical aspects of NHSBSP quality assurance in the breast screening unit

The NHSBSP is a quality assured programme. Thus, any surgeon participating in the programme and treating screening patients must participate in the 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 surgeons' QA group. Particular aspects of the role of a breast screening surgeon require special attention and these are professional updates and liaison, in which regular participation is expected, cooperation and participation with data collection exercises, and training. In addition, the lead surgeon in a breast screening unit takes on particular responsibilities, which are described below (see section 5.2.3).

5.2.1 Professional updates and liaison

All surgeons involved in the NHSBSP should normally be present at more than 50% of meetings of the regional surgeons' QA group in a three year period and at least 50% of all relevant meetings in a three year cycle. These are the regional surgeons' QA meeting, the ABS at BASO conference and annual general meeting, 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.

5.2.2 Data collection and audit

Surgical data in a standard form are collected on the national breast screening (IT) system (NBSS). The current data collection form is shown in Appendix 1. Notes on completion of the clinical record are shown in Appendix 2.

The NHSBSP has established a major audit series in which surgeons have played a highly significant role. Each screening programme is routinely audited through these, which include aggregated information on every woman invited and screened by the NHSBSP in any given year. The data include details of treatment and of the eventual pathology of any cancer found. The surgical contribution is an essential component of this data collection and audit exercise. The returns are eventually signed off by the director of the breast screening unit and validated by the local QA team. The data are then published in the annual statistical bulletin of the NHSBSP compiled by the Health and Social Care Information Centre and in the NHSBSP annual review.^{11,12}

In addition to this overall data collection and audit exercise, the ABS at BASO has for some years worked with the NHSBSP to produce the annual audits of treatment and survival of women with screen-detected breast cancers. They have become the pre-eminent audits of breast cancer treatment, and efforts have been made to establish a similar quality audit for women who present symptomatically, the Breast Cancer Clinical Outcome Measures (BCCOM) audit.¹³ Efforts are now being made to bring these together under the auspices of the National Cancer Intelligence Network (NCIN), which was launched in June 2008.¹⁴

Participation in the NHSBSP/ABS at BASO 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 the completion, verification and submission of these screening audits in a timely fashion to the regional QA reference centre. However, it is recognised that appropriate IT and administrative support is required for this responsibility to be discharged effectively. In addition, surgeons will also in their symptomatic practice 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 a further area where surgical involvement and commitment to the process of data collection is vital.¹⁵

5.2.3 Training

The management of patients requiring surgery as a result of the screening programme should be carried out only by surgeons who have acquired the necessary specialist knowledge and skills. Surgeons involved in screening should have attended an approved multidisciplinary training course.

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 review clinics.

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

5.2.4 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, participating in the expected number of SHA-wide educational and audit activities and monitoring and submitting accurate audit data to the QA reference centre. 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. The contribution of each surgeon will be monitored by the QA team and lead surgeon.

5.3 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.

5.3.1 Routine audit of surgical performance

Surgical performance in breast screening is measured routinely by the regular review of data on biopsy, treatment and follow up of each case of breast cancer diagnosed by a breast screening unit. As described in section 5.2.4, one surgeon in each unit is responsible for that unit's surgical data collection and audit. Participation in the NHSBSP/ABS at BASO audit is compulsory, and audit details for each unit must be reported and discussed at least annually at a meeting of the regional surgical coordinating group convened by the regional surgical coordinator. The QA team will check that the unit's surgeons are participating in the NHSBSP/ABS at BASO audit and in the regional review of audit data.

5.3.2 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, treatment and follow up of women with screen-detected cancers, including the following areas:

- surgical staffing
- arrangements for assessment clinics
- availability of counselling
- waiting times for diagnostic and therapeutic surgery
- arrangements for follow up
- collection and audit of surgical data
- MDT meetings
- participation in clinical trials.

A questionnaire for use in preparing for a visit and as a checklist during the visit is attached at Appendix 3. The purpose of this questionnaire is for the visitor to have a structure on which to ask questions about the unit being visited. The questionnaire must be completed and returned by the lead unit surgeon to the visiting QA surgeon at least six weeks before the QA visit. The questions should be seen as core questions, which can be expanded as necessary. The surgeon being visited should use the interview to explain subtle difficulties or problems that may have arisen and the visitor should try to see how any local difficulties can be resolved.

5.3.3 Case review

The visiting QA surgeon should review a number of selected cases with the screening unit surgeons. Cases for review should include, for each surgeon, at least five sets of case notes for women diagnosed with breast cancer and at least one further set of case notes from a woman screened and assessed who underwent surgical management and was not found to have malignant disease. Cases for review must be anonymised. The review should include consideration of the following points:

- How many times did the woman attend the assessment clinic?
- How many non-operative biopsies were performed?
- Was a non-operative diagnosis made, and if so how?
- What was the waiting time between diagnosis and treatment?
- Who performed the surgery?
- Was there evidence of discussion of treatment options, including the option of breast reconstruction if mastectomy was performed?
- Was treatment completed at the first operation or was a further operation needed to obtain clear margins for malignant disease?
- Was the non-operative diagnosis confirmed?
- Was adequate axillary lymph node staging performed for women found to have invasive cancer?
- Was there an appropriate referral for oncology?
- How was follow up including radiotherapy, managed?

5.3.4 Symptomatic care and peer review

Occasionally during routine QA of the screening programme, issues might arise about care of women who present symptomatically. These should be raised as appropriate with the trust medical director and the local cancer peer review team for further action where necessary.

6 ACHIEVING THE OBJECTIVES AS A NATIONAL PROGRAMME

6.1 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 at BASO 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 at BASO has responsibility for:

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

6.2 Clinical trials and prospective studies

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

The National Cancer Research Network (NCRN) Breast Clinical Studies Group annual report includes a listing of all open trials.¹⁶

In addition, the NHSBSP sponsors and supports the Sloane Project, which aims to include all cases of in situ disease and atypical hyperplasias diagnosed in the breast screening programme.¹⁷

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APPENDIX 1: NBSS SURGERY FORM

SURGERY FORM

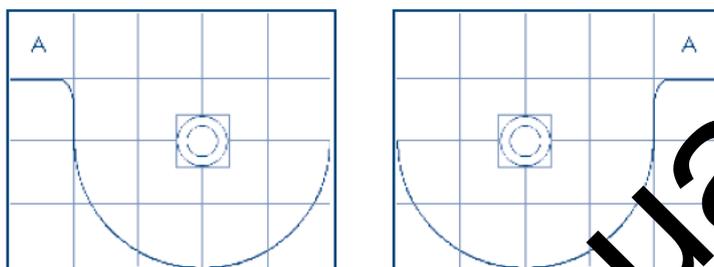
Page 1 of 3

Surname:
Forenames: Date of Birth:
SX Number: NHS Number:

SURGERY PROCEDURE

Date Performed: Location: Consultant: Surgeon:
Hospital Code: Hospital Number: What for: Diagnosis Treatment
Local Trial Code: In National Trial: Which Trial:
Side Assessed: Right Left

Lesions and Abnormalities:



Applies To All Lesions:

LESION OR ABNORMALITY

Surgical Procedures

Diagnostic: Additional:
Treatment: Additional:
Breast Reconstruction: Date Radiotherapy Started:
Staging and Therapeutic:
Non-Surgical Treatments:
Procedure Comment:

Pathology Report

Date Reported: Report Number:
Pathologist: Laboratory:
Specimen Radiograph?: No Yes
Mammo Abnormality?: No Unsure Yes
Histological Calcification: Absent Benign Malignant Both
Specimen Type: Specimen Weight (gm):
Auxiliary Procedures:

Benign Lesions

Benign Lesions?: No Yes
Benign Lesions:
Other Benign Lesion:
Epithelial Proliferation:

Withdrawn January 2021

Surname:
Forenames: Date of Birth:
SX Number: NHS Number:

Malignant Lesions

Malignant Lesions?: [] No [] Yes
In Situ Carcinoma Not Present: []
In Situ Components: [] Ductal [] Lobular [] Paget's
DCIS Grade: [] High [] Intermediate [] Low [] Not assessable
DCIS Growth Pattern(s):
Other Growth Pattern:
Size (mm) if Ductal:
Microinvasion: [] Not present [] Present [] Possible

Malignant Invasive Lesions

Invasive Carcinoma Not Present: []
Invasive Tumour Size (mm):
Whole Tumour Size (mm):
Invasive Tumour Type: [] Ductal/NST [] Pure Special Type [] Mixed [] Other
Other Invasive Type:
Invasive Components: [] Tubular/cribriform [] Lobular [] Mucinous [] Medullary like
[] Ductal/NST [] Other
Other Component(s):
Invasive Grade: [] I [] II [] III [] Not assessable
Disease Extent: [] Localised [] Multiple [] Not assessable
Vascular Invasion: [] Not present [] Possible [] Present

Axillary etc,

Axillary Nodes Present: [] No [] Yes Total [] +ve [] Single Node Type:
Other Nodes Present: [] No [] Yes Total [] +ve [] Site:
Excision Margins: [] Not to margin [] Reaches margin [] Uncertain Excision Distance:
Oestrogen Receptor: [] Positive [] Negative [] Not Performed Quick (Allred) Score:
Progesterone Receptor: [] Positive [] Negative [] Not Performed Quick (Allred) Score:
HER2 Status: [] Positive [] Negative [] Borderline [] Not Performed Score:

Opinion

Comments/additional information: []

Withdrawn January 2021

Surname:
Forenames: Date of Birth:
SX Number: NHS Number:

Cancer on KC62:
Histological Diagnosis: H1 Normal H2 Benign H5 Malignant H0 Cannot report

Lesion Header

Type of Site: Single Multiple
Needs Localising: Localisation: X-Ray Guidance Ultrasound Guidance Skin Marker

Lesion Notes:

Lesion Description: Asymmetry Calcification only Cyst Distortion Lymph Node
 Mass Mass with calcification Clinical abnormality
 Other:

CLOSE EPISODE

Date Episode Closed: Responsible Person: Clinical Team:
Final Action: RR - Routine Recall EC - Short Term Recall
Recall Due Date:
Recall Reason: Woman's Choice Clinical Other:

Withdrawn January 2021

APPENDIX 2: NOTES ON COMPLETION OF THE CLINICAL RECORD ON NBSS

These notes are adapted from pages 65–68 and 115–116 of the FS4068 clinical module redesign functional specification (available on the NBSS website: www.nbss.nhs.uk).

For each field specified, there is a record type indicator and an indicator of whether the item is mandatory or optional. There are also field notes. These are explained below:

R = Record

This indicates the kind of record the data item value belongs to.

R	Record	Where the field is stored
E	Episode	The value applies to the episode
P	Procedure	The value applies to the procedure
S	Side	The value applies to a side in this procedure
L	Lesion Header	The lesion field value is shared by all procedures
LP	Lesion Procedure	The lesion field value only applies to this procedure
–	None	The value is not stored in the database

M = Mandatory/optional indicator

This indicates whether a value is required.

M	Mandatory
	Blank means the mandatory/optional setting is the same as current screen
M	Mandatory, a value must always be entered if the field is enabled
N	Normally mandatory but optional if the field is currently empty. This is used to make a field mandatory for new records while allowing null (empty) values to be retained for historical records. The 'N' flag works only for radio buttons. The system shows 'NS' (Not Specified) at the end of the list and makes 'NS' the default if the field is empty (null). 'NS' is not shown if the field has a non-null value or a non-null default.
O	Optional, entry of a value is optional some or all of the time
R	Field is read-only
–	Not applicable

Notes = field notes

Field notes describe defaulting, special conditions, formatting, validations or special processing. If there are no notes, the field is the same as the current screen.

When the field notes list codes and descriptions, they are listed in the order they will appear in a dropdown list or multiselect pop-up window, for example:

NO	No additional treatment procedures
GU	Guidance by ultrasound
GX	Guidance by x-ray
SX	Specimen x-rayed

Surgical procedures fields

Field	R	M	Notes
Diagnostic	LP		<p>The main diagnostic biopsy procedure. Codes and descriptions are:</p> <p>EXU Excision biopsy (NEW)</p> <p>EXB Excision biopsy palpable</p> <p>EXI Excision biopsy nonpalpable</p> <p>The screen dropdown list shows only descriptions. The procedure description is shown in the lesion list 'Surgical Procedure' column if a description was not determined from treatment (see below). If the diagnostic value is also blank, the lesion list 'Surgical Procedure' caption is 'not specified'</p>
Additional Diagnostic	LP		<p>One or more additional diagnostic biopsy procedures. Codes and descriptions are:</p> <p>AX Axillary node sampling</p> <p>FB Frozen section – benign</p> <p>FD Frozen section – diagnosis deferred</p> <p>FM Frozen section – malignant</p> <p>GU Guidance by ultrasound</p> <p>GX Guidance by x-ray</p> <p>SX Specimen x-rayed</p> <p>Frozen section is still performed occasionally.</p>

Withdrawn January 2021

Surgical procedures fields continued

Field	R	M	Notes
Treatment	LP		<p>The main treatment procedure. Equivalent to 'Treatment Procedure' but has fewer codes and descriptions are:</p> <p>NON No surgical procedures IBT Initial biopsy was treatment WLE Wide local excision/seg/quad RLE Repeat WLE to clear margins TMX Total mastectomy SCM Subcutaneous mastectomy EXP Excision of benign lesion (patient choice) OTH Other</p> <p>The screen dropdown list only shows descriptions. 'EXP' is a new option. An operative procedure to remove a benign lump is usually a 'Diagnosis' and recorded in the 'Diagnostic' field with a code such as 'EXU'. These occur when there is no definite B5/C5 diagnosis and a definitive diagnosis is needed. Occasionally, benign operations are performed when there is a definitive diagnosis (B2). These are recorded as 'Treatment' and 'EXP' when the patient choice to have the lesion removed.</p> <p>The procedure description is shown in the lesion list 'Surgical Procedure' column unless Treatment is IBT, NON or blank. If treatment is IBT, NON or blank, the description comes from the 'Diagnostic' procedure.</p>
Additional Treatment	LP	O	<p>Other procedures associated with treatment. Codes and descriptions are:</p> <p>NO No additional treatment procedures GU Guidance by ultrasound GX Guidance by x-ray SX Specimen x-rayed</p> <p>'NO' cannot be entered in combination with other codes.</p>
Breast Reconstruction	P		<p>Codes and descriptions are:</p> <p>NO No reconstructive procedures SP Subpectoral implant LD LD flap with implant LN LD flap without implant TR TRAM flap DP DIEP flap OT Other</p> <p>The screen dropdown list shows only descriptions.</p>

Withdrawn January 2021

Surgical procedures fields continued

Field	R	M	Notes
Staging and Therapeutic	LP	O	<p>Codes and descriptions are:</p> <p>NL No lymph node procedures</p> <p>AX Four node axillary sampling</p> <p>AY Four node axillary sampling blue dye (NEW)</p> <p>SB Sentinel node biopsy*</p> <p>SD Sentinel node biopsy blue dye (NEW)*</p> <p>SI Sentinel node biopsy radioisotope (NEW)</p> <p>SX Sentinel node biopsy dye and isotope (NEW)</p> <p>AC Axillary lymph node clearance</p> <p>IM Internal thoracic node sampling</p> <p>OT Other nodes biopsied</p> <p>*Under review</p> <p>*'NL' cannot be entered in combination with other codes. The screen allows only one axillary procedure (AX, AY or AC) and one sentinel node procedure (SB, SD, SI or SX).</p>
Non-Surgical Treatments	LP	O	<p>Codes and descriptions are:</p> <p>NO No non-surgical treatments (NEW)</p> <p>CA Pre-op chemotherapy</p> <p>CB Post-op chemotherapy</p> <p>EA Pre-op endocrine (NEW)</p> <p>EB Post-op endocrine</p> <p>HA Other pre-op hormone therapy (NEW)</p> <p>HB Other pre-op hormone therapy (NEW)</p> <p>TA Pre-op Herceptin (Trastuzumab) (NEW)</p> <p>TB Post-op Herceptin (Trastuzumab) (NEW)</p> <p>GA Other pre-op growth factor (NEW)</p> <p>GB Other post-op growth factor (NEW)</p> <p>RB Post-op radiotherapy</p> <p>OA Other pre-op non-surgical treatments (NEW)</p> <p>OB Other post-op non-surgical treatments (NEW)</p> <p>A similar list of options is available at the 'Treatment' prompt in the MDT meeting screen.</p> <p>*'NO' cannot be entered in combination with other codes.</p>
Date Radiotherapy Started	LP	O	<p>New field that has been added for BASO reporting. It is enabled if 'non-surgical treatments' includes 'RB' or blank and disabled if there is no 'RB'. Cannot be in the future. Cannot be before the 'episode start date'.</p>
Procedure comment	LP		

Specimen type

The system automatically derives the specimen type and makes it 'read only' if it can derive a specimen type from the following rules.

Rule	Condition	Specimen type
1	Treatment procedure is RLE (repeat WLE to clear margins) or WLE (wide local excision/seg/quad)	WX
2	Treatment procedure is SCM (subcutaneous mastectomy) or TMX (Total mastectomy)	MS
3	Diagnostic procedure is EXB (excision biopsy palpable)	OB
4	Diagnostic procedure is EXI (excision biopsy impalpable)	LI

Axillary procedures

The system automatically derives a list of axillary procedures specimen types and makes the field 'read-only' if it can derive a value from the following rules.

Rule	Condition	Axillary procedure
1	Staging and Therapeutic procedures include AC (axillary lymph node clearance)	AC
2	Staging and Therapeutic procedures include one of the axillary sampling codes AX or AY or Additional Diagnostic procedures include AX (axillary node sampling)	AS
3	Staging and Therapeutic procedures include one of the sentinel node biopsy procedure codes SB*, SD*, SI or SX. *under review.	SB
4	Staging and Therapeutic procedures is NL (no lymph node procedures)	NP

Withdrawn January 2021

APPENDIX 3: NHSBSP NATIONAL COORDINATION GROUP FOR SURGEONS IN BREAST SCREENING

QA Visit Questionnaire

Name of unit visited:..... Date:.....

Name of visiting surgeon:.....

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 in place 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 above take place at the first visit for assessment? If no please explain the non-operative visits made by a patient before surgery.

.....
.....
.....

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

.....
.....

7.

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

.....

b) Does the nurse meet current nursing PREP requirements?

.....

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

.....
.....

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

.....

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

.....
.....

10. Are you satisfied with the service you receive in respect of cytology and core biopsy reporting?

.....
.....

Withdrawn January 2021

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
.....
- c) average waiting time between diagnosis and first definitive therapeutic intervention
.....
- d) percentage of patients with a positive non-operative diagnosis
.....
- e) treatment of DCIS
 - i) total no. of cases
 - ii) no. and % mastectomies
 - iii) no. and % WLEs.....
 - iv) no. and % other treatments.....
- f) treatment of invasive cancers
 - i) total no. of cases.....
 - ii) no. and % simple 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 immediate breast reconstruction
.....

Withdrawn January 2021

h) number of operations per patient for the treatment of screen-detected breast cancer

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

i) outcome of patients surgically treated for screen detected breast cancer

i) total no. of screen detected cancers

ii) no. of patients disease free (at specified date)

iii) no. of patients with recurrent diseases (at specified date)

iv) no. of patients died (before specified date)

12. Are multidisciplinary meetings held with radiologists, pathologists and radiotherapists/oncologists?

Yes/No

If not, why not?

.....

a) How often are they held?

.....

b) Are all non-operative patients discussed?

.....

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

.....

d) Who keeps 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?

.....

b) Are there any problems with trial entry?

.....

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

.....

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

.....

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

.....

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

.....
.....

21. What do you believe are the weaknesses of this unit?

.....

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

.....
.....
.....

Sign off

LEAD SURGEON DATE

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