



Guidelines

Surgical guidelines for the management of breast cancer

 Association of Breast Surgery at BASO
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INTRODUCTION

The publication of the first widely disseminated guidelines for surgeons on the management of breast cancer in the United Kingdom in 1992 followed the introduction of the National Health Service Breast Screening Programme (NHSBSP) in 1987 and focussed on screen-detected breast cancer.¹ Subsequently guidelines for surgeons on the management of symptomatic breast disease were published in 1995.² The Breast Group at BASO (now the Association of Breast Surgery at BASO) was closely involved in the initiation and drafting of both documents. Updated versions of both screening and symptomatic guidelines have subsequently been published.

In 1995 the Chief Medical Officer published a Policy Framework for commissioning cancer services, which suggested that the care of malignant disease should be delivered through Cancer Centres and Cancer Units³ and that breast cancer services should be managed through specialised departments. Equivalent standards of care should be delivered in Cancer Units as in Cancer Centres, although some facilities such as radiotherapy may not be available locally in cancer units. In geographically isolated units multidisciplinary consultation by telemedicine may be appropriate to ensure expert care where the local population is small.

In 2000, the NHS Cancer Plan was published and promised improved access and waiting times for people already diagnosed with or thought to have cancer.⁴ In 2002, the National Institute of Clinical Excellence produced updated guidelines on improving the outcomes for patients with breast cancer.⁵ Subsequently in 2007, the Department of Health published their new cancer plan – The Cancer Reform Strategy.⁶ This aims to reduce morbidity and mortality from cancer, by promoting cancer prevention, improving screening, early diagnosis and treatment.

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 new ‘Surgical Guidelines for the Management of Breast Cancer’ reflect this. They should be used in conjunction with the updated ‘Quality Assurance Guidelines for Surgeons in Breast Cancer Screening (Fourth Edition)’.

SECTION 1: MULTIDISCIPLINARY CARE*The breast multidisciplinary team (MDT)*

It is now widely accepted that breast care should be provided by breast specialists in each discipline and that multidisciplinary teams form the basis for best practice. The constituent members of the Breast Team may be conveniently divided into two separate but inter-dependent groups.

- *Diagnostic Team*
- *Cancer Treatment Team*

Diagnostic Team

As most patients do not have breast malignancy, the role of the breast clinic is both to diagnose breast cancer and to treat and reassure patients with benign breast disorders. The key component members of this group are:

- *Breast Specialist Clinician* normally a Consultant Surgeon with an interest in breast disease and their team which may include Associate Specialists, Breast Clinicians, Staff Grade Surgeons and Specialist Trainees.
- Specialist Radiologist and Radiographer
- Pathologist (Cytopathologist and/or Histopathologist) and Laboratory Support Staff
- Breast Care Nurse
- Nurse Practitioner
- Clinic Staff
- Administrative Staff
- Dedicated MDT Co-ordinator

Cancer Treatment Team

This will include members of the Diagnostic Team as well as the following:

- Clinical Oncologist
- Medical Oncologist
- Plastic and Reconstructive Surgeon and/or Oncoplastic Breast Surgeon
- Medical Geneticist
- Data Management Personnel
- Research Nurse
- Lymphoedema specialist
- Medical Prosthetist
- Clinical Psychologist
- Palliative Care Team

Multidisciplinary team meetings

Consultants and other team members within the breast unit must have contractual time for attendance at the multidisciplinary team meeting. The MDT meeting is by definition a fixed clinical commitment. For medical staff, this should be counted as one session or Programmed Activity (PA). This reflects the time involved in preparation, the meeting itself and post-meeting administration. It is essential for trainees within breast surgery and its related disciplines to attend the MDT meeting. A record of attendance should be kept, and trainees should record attendance in their logbook. The conclusions of patient discussion should be recorded in the case notes.

A designated member of the clerical team (MDT Co-ordinator) should have the responsibility to co-ordinate this process. This may be shared with a secretarial or data management function. This is an important, responsible role and appropriate time should be available to discharge this effectively.

Video-conferencing facilities should be available to permit discussion between units, if required. This is particularly important for geographically isolated units. However, this will also allow discussion between Cancer Centres and smaller Cancer Units.

Although each unit may hold one MDT meeting each week, patient decisions can be categorized as either

- a Diagnostic
- b Treatment planning
- c Re-presentation

a Diagnostic

This is where new cases are discussed. Discussion should be considered for all cases where a needle biopsy has been carried out and the diagnosis is not clearly benign. The imaging and pathology (core biopsy +/- fine needle aspiration) results should be available. All patients diagnosed with breast cancer should be discussed prior to instigation of therapy – whether surgery, neoadjuvant or primary medical therapy. Results of all required prognostic and predictive factors (including ER status and ideally HER2 status and any others used in that unit according to local guidelines) should be available for this discussion.

b Treatment planning

This is also known as the ‘post-operative results’ MDT, whereby the pathology results of definitive treatment (usually surgery) are discussed and appropriate adjuvant treatment options decided. Results of all required prognostic and predictive factors (ER, HER2, and any others used in that unit according to local guidelines) must be available for this discussion.

c Re-presentation

This is where a previously treated patient re-presents with symptoms. A common instance of this might be the re-presentation of a patient with suspicious symptoms and a diagnosis of metastatic disease.

Multidisciplinary team meetings.

Quality objectives	Outcome measures
A MDT meeting should take place to discuss patient management, before treatment options are discussed with the patient	A 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

SECTION 2: DIAGNOSIS

Wherever possible, a non-operative breast cancer diagnosis should be achieved by triple assessment, (clinical and radiological assessment followed by core biopsy and/or fine needle aspiration). Whilst core biopsy is preferable due to the additional information it can provide, there may be circumstances where only a fine needle aspiration is possible.

A non-operative diagnosis should be possible in the vast majority of invasive breast cancers, with a minimum standard of achieving this in at least 90% of cases and a target of more than 95%. The majority of non-invasive breast cancers will be screen-detected and impalpable, making a non-operative diagnosis potentially more difficult. The minimum standard for non-operative diagnosis is at least 85% of cases for non-invasive cancers with a target of more than 90%.

Diagnostic excisions

Diagnostic excision biopsy is now relatively unusual, with the advent of triple assessment and also the increasing use of vacuum assisted biopsy for difficult cases. However, some breast lesions may still require diagnostic excision, if the core biopsy or FNA is not benign. Hence lesions graded as B3/4 or C3/4 may still need to be removed for definitive histology. Such lesions are more likely to emanate from the NHSBSP than the symptomatic clinic. To minimize patient anxiety, an operation for diagnostic purposes should be within two weeks of the decision to operate. For patients having surgical removal of a pathologically proven benign lesion the 18 week target waiting time will apply.

All diagnostic biopsy specimens should be weighed. More than 90% of diagnostic biopsies for impalpable lesions, which subsequently prove to be benign should weigh less than 20 g in line with the current Quality Assurance Guidelines for Surgeons in Breast Cancer Screening. Any benign diagnostic resection specimen weighing more than 40 g should be discussed at the post-operative MDT meeting and any mitigating reasons recorded, and if a screening case, also discussed at the next Quality Assurance visit to that unit.

Frozen section pathology

Frozen sections with immediate pathological reporting at surgical breast biopsy should not be performed except in very unusual circumstances and the reasons documented.

Diagnosis.

Quality objectives	Outcome measures
To minimise the cosmetic impairment of diagnostic open biopsy	The fresh weight of tissue removed for all cases where a diagnostic open biopsy is performed should be recorded ≥90% of open surgical biopsies carried out for diagnosis, which prove to be benign, should weigh ≤20 g All cases where open surgical diagnostic biopsies which prove to be benign and weigh >40 g should be discussed at the post-operative MDT meeting and any mitigating reasons recorded.
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 2 weeks. Minimum standard – ≥90% within 2 weeks Target – 100% within 2 weeks
To minimise unnecessary surgery, ie open surgical diagnostic biopsies that prove to be malignant	Invasive breast cancers should have a non-operative pathological diagnosis Minimum standard – ≥90% Target – ≥95% Non-invasive breast cancers should have a non-operative pathological diagnosis Minimum standard – ≥85% Target – ≥90%

SECTION 3: TREATMENT PLANNING AND PATIENT COMMUNICATION

Each breast unit must have written guidelines for the treatment of breast cancer, which have been formulated and agreed by the breast multidisciplinary team. The treatment of patients should usually follow these guidelines, although it is accepted that there may be reasonable exceptions. The reasons for not following guidelines should be discussed at the MDT meeting and documented.

Following confirmation of a breast cancer diagnosis and appropriate MDT discussion to plan management, the results should be discussed with the patient. Patients should be encouraged to bring a partner or friend with them when the results are being discussed. The person conducting the consultation should be a member of the Breast MDT and the breast care nurse should usually be present. It should take place in an appropriate environment with adequate privacy. The follow up arrangements should be clear and the patient must know how to access the breast care nurse and other relevant components of their care plan.

Patients must be given adequate time, information and support in order to make a fully informed decision concerning their treatment. This must include discussion of suitable treatment options with the surgeon in liaison with the breast care nurse. The treatment options offered should have been agreed at a MDT meeting and the decisions agreed with the patient should be recorded. In the event of a patient refusing the recommended treatment options this should be recorded.

Close communication must be maintained between surgeons and oncologists to plan primary treatment and to facilitate subsequent adjuvant therapy. A care plan for each patient must be drawn up. It must take account of factors predictive of both survival and of local or regional recurrence, the age and general health of the patient, the social circumstances and patient preferences. Treatment planning should allow adequate time for discussion of oncoplastic/reconstructive surgical options for those women who wish to consider it.

Breast cancer at diagnosis can be broadly classified into three clinical categories:

(A) Operable primary breast cancer

The majority of breast cancer cases, presenting symptomatically or diagnosed through breast screening, will fall into this category. Surgery will usually be the first treatment and will be discussed in further detail in these guidelines. Neoadjuvant endocrine treatment may be appropriate in some instances to downstage bulky disease to facilitate breast conserving surgery in post menopausal women with ER positive breast cancers. There is currently no consensus regarding the use of neoadjuvant chemotherapy in this circumstance. However the available data from randomised trials shows that breast conserving surgery after neoadjuvant therapy is associated with a significantly increased risk of local recurrence. Where neoadjuvant therapy is being considered the increased risk of local recurrence should be discussed with women and taken into consideration given the recent reports from the Oxford overview which shows that the avoidance of local recurrence in the conserved breast prevents about one breast cancer death for every four such recurrences avoided.⁷

(B) Locally advanced primary breast cancer

The management of locally advanced primary breast cancer should be multidisciplinary and will initially require a core biopsy and staging investigations. In some patients medical treatment (hormonal/chemotherapy) and/or radiation therapy may be the most appropriate initial treatment. The management of locally advanced primary breast cancer will not be discussed further in these guidelines.

(C) Metastatic breast cancer

Following the symptomatic presentation of distant metastases, average life expectancy is approximately 2 years, with virtually all patients eventually dying from breast cancer. The aim of treatment is to palliate symptoms and to maintain the highest possible quality of life. The management of patients with metastatic breast cancer should be multidisciplinary. Although the majority of patient care is likely to be delivered by oncologists and the palliative care team some surgeons with established experience in this field may continue to be involved in the multidisciplinary team. In addition all breast surgeons need to be involved with the local control of the disease. The management of metastatic breast cancer will not be discussed further in these guidelines.

Recurrent breast cancer

A multidisciplinary approach is needed in the management of patients with recurrent breast cancer. All patients presenting with recurrent breast cancer should be restaged prior to definitive management. A significant proportion of patients presenting

with ‘local recurrence’ will have systemic relapse as well. Those patients with widespread disease should be managed by systemic therapy if possible. The management of recurrent breast cancer will not be discussed further in these guidelines.

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 a multidisciplinary team	The management of all patients with newly diagnosed breast cancer should be discussed at a MDT meeting and the conclusions documented in each patient’s notes.

SECTION 4: ORGANISATION OF BREAST CANCER SURGICAL SERVICES

Personnel

Surgical treatment of patients with breast cancer must be carried out by surgeons with a special interest and training in breast disease^{8–10} (Level 3 evidence). Each surgeon involved in the NHS BSP should maintain a surgical caseload of at least 10 screen-detected cancers per year, averaged over a three year period. It is expected that surgeons with low caseloads should be able to demonstrate an annual surgical workload of at least 30 treated breast cancers. Breast surgeons should work in breast teams, which have the necessary expertise and facilities for a multidisciplinary approach.

Waiting times for surgical treatment

When a decision has been reached to offer surgical treatment, patients should be offered a date for operation rather than be placed on a waiting list. Reconstruction procedures will require logistical planning but should not lead to unnecessary delay. All diagnostic and therapeutic operations are urgent.

The NHS Cancer Plan⁴ states that patients should have a maximum wait of 31 days from ‘decision to treat’ to first treatment. In 2002, this standard was extended to a maximum 62 days wait from urgent GP referral to first treatment. A similar 62 days wait target now applies to screen detected breast cancers from December 2008, following publication of the Cancer Reform Strategy.⁶ To achieve these targets resources must be available, and in particular staffing levels must be appropriate. The ‘decision to treat’ is taken as the date on which the patient is informed by the treating clinician that they require treatment. As previously stated, an operation for diagnostic purposes should be carried out within two weeks of the decision to operate.

Pre-operative investigations

A pre-operative search for occult metastases by bone scan and liver ultrasound does not yield useful information in patients with operable primary breast cancer¹¹ (Level 3 evidence). These investigations should not normally be carried out unless the patient is symptomatic, partaking of a clinical trial or is recommended for neo-adjuvant therapy.^{12,13} A pre-operative chest x-ray is of limited value and its use should be agreed by local protocol. The patient should have a full blood count, liver function tests and routine biochemistry and any abnormalities should be investigated appropriately.

Organisation of surgical services.

Quality objectives	Outcome measures
To ensure specialist surgical care	Breast cancer surgery should only be performed 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 2 weeks. Minimum standard – $\geq 90\%$ within 2 weeks Target – 100% within 2 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 with 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

SECTION 5: SURGERY FOR INVASIVE BREAST CANCER

Type of breast surgical procedure

Long term follow up of randomised clinical trials have reported similar survival rates for women treated by mastectomy or breast conservation surgery.^{14–16} However all of these studies had selection criteria and indeed the vast majority of patients in these studies presented with tumours <2.5 cms.

Accurate pre-operative assessment of the size and extent of the tumour is essential for deciding whether breast conservation surgery is an alternative option to mastectomy. Routine methods for assessing the extent of disease in the breast are clinical examination, mammography and ultrasound. In a significant number of cases the true extent of disease is underestimated, particularly with invasive lobular cancer. Selective use of magnetic resonance imaging (MRI) may be useful in planning surgical treatment and in particular if: there is a discrepancy between the clinical and radiological estimated extent of disease; if there is a dense breast pattern on mammography; or the diagnostic core biopsy suggests an invasive lobular cancer. The decision to offer MRI should be discussed at the MDT meeting and be according to local guidelines.

Whilst many women may be suitable for breast conservation surgery, various factors (eg biological, patient choice) may lead to some women being advised or choosing to have a mastectomy for their disease.

Wherever possible, patients should be offered an informed choice between breast conservation surgery and mastectomy. Patients choosing or advised to have mastectomy for invasive breast cancer should have the opportunity to discuss whether breast reconstruction is appropriate and feasible. The reasons for not offering choice and/or breast reconstruction to a patient should be documented in the patient's case notes.

Margins of excision

Patients undergoing breast conservation surgery should routinely have malignant tumours excised with microscopically clear radial margins. Close margins at the chest wall or near the skin may be less important. Where breast tissue is to be moved at the time of surgery (eg oncoplastic techniques) particular consideration must be given to ensuring that further excision of involved margins can be easily carried out without a patient per se being committed to a mastectomy.

Intra-operative specimen radiography is mandatory for impalpable lesions requiring radiological localization, and recommended for all wide local excision procedures. 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. Interpretation of specimen radiographs must be clearly recorded. If this is done by the operating surgeon, the result must be confirmed by the radiologist at the subsequent multidisciplinary team meeting. If the radiologist reports the film at once, no more than 20 minutes should elapse before the reported film is received by the operating surgeon. If a specimen radiograph is performed, this should be available to the reporting pathologist. The surgeon should orientate and mark the specimen prior to delivery to the pathologist. The breast unit must have a clear protocol for specimen orientation and the handling of pathological specimens. Histologically involved margins lead to an excessively high risk of local recurrence, even if adjuvant radiotherapy is given. Approximately one in four patients with later local recurrence will succumb to their disease, who otherwise would not have died of breast cancer if they had not developed a local recurrence.⁷

There are no data to support a specific margin of excision. There are no randomised trials of margins of excision. While further occult foci of disease can be found more than 2 cm from the supposed margin in up to 43% of patients¹⁷ the wider the margin the less occult foci are found. Whilst NICE have previously recommended a minimum margin of 2 mm,⁵ there are no data to substantiate this. Units should have local guidelines regarding acceptable margin width and individual cases should be discussed at the treatment MDT meeting. If, after MDT meeting discussion, the margin of excision is deemed to be inadequate then further surgery to obtain clear margins should be recommended.

Marking of surgical cavities in breast conservation surgery

New advances in radiation therapy have led to more accurate and consistent planning and delivery of therapy. Intensity modulated radiotherapy (IMRT) is now increasingly used to deliver satisfactory treatment doses to the clinical tumour volume, whilst also providing the ability to spare normal tissues. Consistent and accurate localisation of the tumour resection bed after breast conservation is important if the full benefits of IMRT and further radiotherapy advances are to be obtained. Previous studies have

shown that estimating the tumour bed from the position of the surgical scar is inaccurate. The marking of the tumour bed is especially important when oncoplastic techniques are used to improve the cosmetic outcome. The insertion of markers, such as surgical clips or gold seeds, in the tumour bed by the operating surgeon provides a way of visualising the tumour bed. Surgical clips are easy and cheap and allow radiotherapy planning either by CT or kilo-voltage exit portals. Surgeons referring to radiotherapy centres using megavoltage exit portals may need to consider the use of gold seeds, as clips cannot always be easily visualised on mega-voltage equipment.

Local recurrence rates

The main aim of surgery is to achieve good local control of both the primary tumour and the regional nodes in the axilla. In patients with operable breast cancer, complete excision of the primary tumour with clear margins is essential. The major randomised trials of breast conservation surgery and radiotherapy versus mastectomy for invasive cancer report local recurrence rates for breast conservation surgery ranging between 3% at 6 years to 17% at 10 years and for mastectomy ranging between 2% at 10 years and 9% at 8 years^{14–16,18} although as noted above the majority of tumours in these trials were <2.5 cms.

However, the START trial has now reported and shows excellent low rates of local recurrence (3.5% at 5 years) following breast conservation surgery in the UK.¹⁹ Hence the recommended minimum standards and targets for local recurrence after breast conservation surgery for invasive cancer have been revised to a maximum of 5% at 5 years and a target of <3% at 5 years.

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	Intra-operative 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 ≤3 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 5 years Target – <3% of patients treated by breast conservation surgery should develop local recurrence within 5 years
To minimise local recurrence after mastectomy for invasive malignancy	Minimum standard – <5% of patients treated by mastectomy should develop local recurrence within 5 years Target – <3% of patients treated by mastectomy should develop local recurrence within 5 years

SECTION 6: AXILLARY NODE MANAGEMENT IN INVASIVE BREAST CANCER

The presence of axillary node metastases is the most powerful prognostic determinant in primary operable breast cancer and its assessment requires histological examination of excised axillary lymph nodes. Appropriate management of the axilla is also important in the prevention of uncontrolled axillary relapse. Axillary relapse is defined as relapse in the axilla itself and does not include supraclavicular recurrence.

Some patients with invasive breast cancer may be diagnosed with axillary disease prior to definitive surgery. The use of pre-operative axillary assessment with ultrasound and appropriate fine needle aspiration (or core biopsy if feasible) can yield a diagnosis of involved nodes in some cases. If a positive non-operative diagnosis of axillary nodal metastasis is made in a patient with early breast cancer, that patient should normally proceed to an axillary clearance. If an axillary clearance is carried out all axillary lymph nodes should be removed unless there are specific reasons or unit policies not to do this. In the latter cases the anatomical level of dissection should be specified in the operation note. The number of nodes retrieved from axillary node clearance histology specimens will be both surgeon and pathologist dependent. However, for a full axillary clearance at least 10 nodes should be retrieved in >90% of cases.

Ideally, all patients with early invasive breast cancer should have axillary staging and if positive for metastasis, treatment for axillary disease. If an axillary staging procedure is not to be carried out the reasons for this should be discussed at the MDT meeting and documented in the patient's case notes.

Complete axillary clearance (level 3) is effective in controlling regional disease. Recurrence rates of 3%–5% at 5 years have been reported,^{20–23} but some of these studies with level 2 clearance included both lymph node negative and positive cases. It is suggested that axillary node recurrence should be less than 5% at five years with a target of less than 3%. Lesser degrees of surgery without axillary radiotherapy lead to correspondingly higher rates of axillary recurrence. The Edinburgh study on patients receiving selective axillary radiotherapy for positive nodes after axillary sampling demonstrated similar control to that of full (level 3) axillary clearance^{20,24} (Level 2 evidence).

In the last few years, sentinel node biopsy (SNB) has become a standard approach for axillary staging. This technique provides accurate assessment of the axilla, with few false negatives and a significant reduction in surgical morbidity, especially lymphoedema.²⁵ Breast surgeons are encouraged to adopt the SNB technique and take part in the NEW START or equivalent training programmes. The combined technique (blue dye and radio-isotope) is the recommended method. Surgeons should be able to achieve minimum standards with a >90% sentinel node identification rates and <10% false negative rates over a minimum 30 case audit series.

Surgical staging of the axillary lymph nodes should be performed according to local protocols. If there is a non-operative diagnosis of invasive malignancy, then an axillary staging procedure should be carried out at the same time as surgery to resect the primary tumour other than in exceptional circumstances eg, prior to immediate LD flap reconstruction. Axillary staging may be achieved by sentinel node biopsy (recommended in the majority), sampling, or clearance. If axillary node sampling is carried out then at least 4 nodes should be obtained. Blue dye may be used to augment axillary node sampling and if used this should be documented in the operation note. Routine use of axillary node clearance as an axillary staging procedure will be over treatment for the majority of patients.

Where the sentinel node is positive (macrometastasis or micrometastasis), further axillary treatment (axillary dissection or radiotherapy) as well as adjuvant systemic therapy is recommended. However, the management of patients with positive sentinel nodes is currently under investigation. The EORTC-AMAROS trial compares axillary clearance versus radiotherapy. The ACOS-OG Z0011 trial compares axillary clearance versus observation only. These studies will not report for some time. The decision to carry out a completion (full) axillary clearance or to give axillary radiotherapy if the sentinel node is positive should be discussed at the MDT meeting and with the patient, be according to local guidelines, and be documented in the patient's case notes. The significance of isolated tumour cells in axillary lymph nodes is currently uncertain and these should be regarded as lymph node negative and routine axillary treatment is not recommended.

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 pre-operative axillary ultrasound scan, and if appropriate 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 nodal metastasis is made in a patient undergoing surgery for breast cancer, the patient should normally proceed to an 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 completion (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% 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% Target – 100%</p> <p>When axillary node sampling is carried out at least 4 nodes should be retrieved</p> <p>Minimum standard – >90% 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 5 years Target – <3% axillary recurrence at 5 years</p>

SECTION 7: SURGICAL MANAGEMENT OF DUCTAL CARCINOMA IN SITU

Ductal carcinoma in situ (DCIS) is a malignant precursor of invasive breast cancer. The aim of surgery is to achieve complete excision of the in situ tumour and to minimise local recurrence. The grade of the tumour²⁶ and clear resection margins (>1 mm margin)²⁷ are important factors in the management of DCIS.

Tumour multifocality is not uncommon and can lead to high local failure rates.²⁸ Approximately 50% of local relapses after treatment for DCIS are invasive and not in situ. The indications for mastectomy are uncertain but extensive micro calcification on the pre-operative mammogram is a risk factor for local recurrence after conservation surgery. High recurrence rates occur with larger tumours (>40 mm diameter) and mastectomy should be considered for such cases. While mammographic findings do not always correspond to pathological size the mammographic size is more commonly an underestimate of the final histological size. If mastectomy is being considered for the treatment of DCIS on the basis of multifocality, then at least two areas of the breast should ideally be biopsied to confirm this.

There have been randomised trials of adjuvant radiotherapy after breast conservation for DCIS. In the EORTC study,²⁷ clear margins (>1 mm) were associated with a local recurrence rate of 15% at 5 years compared to 36% in patients with close or involved margins (<1 mm or frankly involved), regardless of the use of radiotherapy. Likewise, low grade DCIS is associated with a low risk of recurrence.

Patients undergoing breast conserving surgery should routinely have the DCIS excised with microscopically clear radial margins. Close margins at the chest wall or near the skin may be less important. Where breast tissue is to be moved at the time of surgery (eg oncoplastic techniques) particular consideration must be given to ensuring that further excision of involved margins can be easily carried out without a patient per se being committed to a mastectomy.

Intra-operative specimen radiography should be carried out for all cases of DCIS treated by breast conservation surgery, the vast majority of which will be impalpable lesions requiring radiological localization. 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. Interpretation of specimen radiographs must be clearly recorded. If this is done by the operating surgeon, the result must be confirmed by the radiologist at the subsequent multidisciplinary team meeting. If the radiologist reports the film at once, no more than 20 minutes should elapse before the reported film is received by the operating surgeon. If a specimen radiograph is performed, this should be available to the reporting pathologist. The surgeon should orientate and mark the specimen prior to delivery to the pathologist. The breast unit must have a clear protocol for specimen orientation and the handling of pathological specimens.

There are no data to support a specific margin of excision. Units should have local guidelines regarding acceptable margin width for DCIS and individual cases should be discussed at the treatment MDT meeting. If, after MDT meeting discussion, the margin of excision is deemed to be inadequate then further surgery to obtain clear margins should be recommended.

Lymph node staging is not normally required for patients with a non-operative diagnosis of DCIS alone. However, some patients may be at high risk of an occult invasive carcinoma being found at subsequent pathological examination. These would include patients undergoing surgery for: an extensive area of microcalcification; a palpable mass; high grade disease; or where micro-invasion or frank invasion is suspected on the non-operative biopsies. In such cases SNB or four node sampling may be considered. Axillary clearance is contra-indicated in the treatment of patients with a non-operative diagnosis of DCIS alone. The decision to carry out an axillary staging procedure should be discussed at the MDT meeting and with the patient, be according to local guidelines, and be documented in the patient's case notes.

The management of screen detected non-invasive breast cancer (and atypical hyperplasias) is the subject of a national audit, the Sloane Project. All breast screening units should participate in this.

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 conservation 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	Intra-operative 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 ≤3 operations
To minimise local recurrence after breast conservation surgery for DCIS	Patients with extensive (>40 mm diameter) or multi-centric 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 pre-operative MDT meeting and recorded in the patient's case notes. Axillary node clearance is contra-indicated 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 5 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

SECTION 8: SURGERY FOR LOBULAR IN SITU NEOPLASIA

Lobular in situ neoplasia, LISN, (formerly known as lobular carcinoma in situ or LCIS) is often an incidental finding and is usually occult. LISN may not be a local malignant precursor lesion, but it does confer an increased future risk, approximately seven-fold, of invasive breast cancer in both breasts^{29–32} (Level 3 evidence). The risk of developing breast cancer is approximately 1% per year.

It is suggested that breast lesions containing LISN should be excised for definitive diagnosis, as some patients may have a co-existing invasive malignancy. The limited data available on LISN suggests that clear resection margins are not required following surgery for LISN alone. A policy of close surveillance after excision biopsy is appropriate (Level 3 evidence).

The management of screen detected LISN is included in a national audit, the Sloane Project. All breast screening units should participate in this.

Recommendations.

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- Patients with a pre-operative diagnosis of LISN should be considered for diagnostic excision biopsy.

 - Post-operative surveillance is appropriate in these patients as they have an elevated risk of subsequent breast cancer.

 - Each breast unit should have agreed surveillance guidelines for patients treated for conditions that lead to an increased risk of later breast malignancy (such as LISN ADH etc.).

 - All breast screening units should participate in the Sloane Project.

SECTION 9: BREAST RECONSTRUCTION

All patients, in whom mastectomy is a treatment option, should have the opportunity to receive advice on breast reconstructive surgery. Not all patients will be physically fit for or wish to consider reconstruction. If this is not available within the breast unit, the breast team should have a recognised line of referral to a breast or plastic surgeon with particular expertise in breast reconstruction. Timely access for patients considering reconstruction is essential in order that they are not discouraged by the process.

For patients, who express an interest in breast reconstruction, discussions should take place on the ideal timing of the reconstruction. This should include the risks and benefits of immediate versus delayed techniques. Ideally breast units should have clinicians with oncoplastic expertise &/or breast surgeons who work with plastic and reconstructive surgeons with an established interest in breast reconstruction, who can provide this service. Where units offer breast reconstruction, adequate facilities, including theatre time and outpatient clinic time to counsel patients prior to surgery should be available. Facilities should be available for revisional surgery.

Further guidance has been published by the Association of Breast Surgery at BASO, the British Association of Plastic, Reconstructive and Aesthetic Surgeons and the Training Interface Group in Breast Surgery: Oncoplastic breast surgery – a guide to good practice.³³

For patients undergoing mastectomy without immediate reconstruction, a service should be provided to supply and fit breast prostheses.

Breast reconstruction.

Quality objectives	Outcome measures
Patients should have access to breast reconstruction surgery	<p>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.</p> <p>Breast Units should have surgeons with oncoplastic experience &/or have the rapid availability of a plastic surgeon</p> <p>Adequate time for consultation and surgery must be available</p>
Patients not undergoing immediate breast reconstruction should be provided with breast prostheses	Breast prostheses should be freely available to patients treated by mastectomy together with easy access to a fitting service

SECTION 10: PERI & POST-OPERATIVE CARE*Peri-operative and follow up care*

Patients should be supported by a breast care nurse or a clinical nurse specialist, who is a member of the breast team and who should have established links with outpatient, ward and community nurses to assist in continuity of care. Following mastectomy (without immediate breast reconstruction), the fitting and supply of breast prostheses should be explained to patients. Patients should be informed about the range of services available to them and be provided with literature to include details of follow up treatment and local self help support groups.

Communication with General Practitioners

The breast team should ensure that primary care practitioners (GPs) receive communications that give them a clear and rapid understanding of the diagnosis, care plan, and toxicity profile of any proposed treatment. It is the responsibility of clinical trialists to ensure that GPs are fully briefed about any trial for which the patient is entered and the potential side effects.

Treatment multidisciplinary team meeting

All patients with breast cancer should have their cases discussed after definitive surgery. This is commonly known as the ‘post-operative results’ MDT meeting. The post-operative pathology results including all required predictive and prognostic markers (ER, HER2, and any others used in that unit according to local guidelines) must be available to allow adequate discussion. Decisions about the need for further surgical treatment and/or adjuvant treatments should be discussed and the decisions recorded in the patient’s case notes. An oncologist should be present at this meeting.

Peri- and post-operative care.

Quality objectives	Outcome measures
To ensure 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

SECTION 11: ADJUVANT TREATMENTS

Written local breast cancer treatment guidelines should identify which patients should be considered for 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 patient’s case notes.

Adjuvant systemic treatments have been shown to reduce the risk of recurrence and to improve overall survival. Adjuvant treatments should not be decided upon based on relative risk reduction calculations. The use of adjuvant treatments should be decided after a calculation has been made of an individual patient’s absolute risk of recurrence and the absolute benefit of a proposed treatment either alone or in combination with another treatment.

Local adjuvant treatment guidelines should include the following areas.

(a) Radiotherapy

Breast radiotherapy for invasive breast cancer

Patients who have undergone breast conservation for primary invasive breast cancer should be treated with adjuvant radiotherapy to the breast^{7,14,15,18} (Level 1 evidence), unless radiotherapy is contra-indicated or the patient is entered into a clinical trial.

Chest wall radiotherapy post mastectomy for invasive breast cancer

Patients treated by mastectomy with higher risk disease may also be considered for adjuvant chest wall radiotherapy. There is evidence of reduced local recurrence with post-operative radiotherapy and of improved survival in patients with higher risk disease.^{34,35} More recent unpublished data, from the Oxford Overview 2005, showed a reduction in local recurrence and improved survival for patients with any node positive disease after mastectomy.¹⁶

Axillary radiotherapy for invasive breast cancer

Patients with histologically negative nodes after adequate surgical axillary assessment should not receive axillary radiotherapy. Node positive patients who have undergone axillary clearance need not be treated with radiotherapy unless multi-disciplinary review suggests that there is a particularly high risk of regional relapse, eg, if extensive extranodal spread of tumour seen. The potential benefit of dual treatment should be balanced against an increased risk of lymphoedema. Most patients with histologically involved axillary nodes following sentinel node biopsy or node sampling should have radiotherapy if a subsequent axillary node clearance has not been carried out. The requirement for radiotherapy to the supraclavicular nodal regions should be determined at the MDT meeting and follow the agreed local guidelines.

Breast irradiation for patients with ductal carcinoma in situ (DCIS)

Patients who have been treated by mastectomy for DCIS do not require adjuvant radiotherapy.

Several published randomised trials and a later meta-analysis of local excision alone versus excision and radiotherapy have demonstrated a significant reduction in the risk of ipsilateral invasive and non-invasive recurrence in the radiotherapy group after long term follow up^{27,36–39} (Level 1 evidence). These studies suggest that radiotherapy reduced the hazard ratio for local recurrence by 60%. While, no difference in overall survival has been noted in the patients treated with radiotherapy none of these trials were powered to show a survival difference. The fact that 50% of local recurrences after breast conservation surgery for DCIS are actually invasive disease and the recent established link between local recurrence of invasive disease and subsequent risk of death from breast cancer should be taken into consideration when deciding whether or not to omit adjuvant radiotherapy following breast conservation surgery for DCIS.

MDT discussion of the need for radiotherapy should take place for all cases of DCIS treated by breast conservation surgery, but the value of radiotherapy will be related to the risk of local relapse and should follow the agreed local guidelines.

Axillary radiotherapy for patients with ductal carcinoma in situ (DCIS)

Axillary radiotherapy should not be given to patients, who have been diagnosed with DCIS alone.

(b) Endocrine therapy

All patients with ER positive invasive breast carcinoma can potentially benefit from hormonal therapy⁴⁰ (Level 1 evidence). Hormonal therapy reduces the hazard ratio of death from breast cancer by approximately 30%. This effect is independent of progesterone receptor status, patient age and concomitant chemotherapy use. A decision whether or not to use endocrine therapy should be based on an assessment of the absolute benefit and the risks or side effects of treatment. Treatment regimes should be described in local protocols.

Current options for endocrine treatment include tamoxifen, aromatase inhibitors (anastrozole, exemestane, letrozole), progestogens, luteinising hormone releasing hormone (LHRH) analogues and oophorectomy by radiotherapy, laparoscopy or open surgery.

The Early Breast Cancer Trialists' Collaborative Group (EBCTCG) Oxford Overview shows that women with ER negative invasive tumours derive no benefit from hormonal therapy (Level 1 evidence). Endocrine treatment should not normally commence until the oestrogen receptor status has been determined.

Bone monitoring, such as dual energy x-ray absorptiometry (DEXA) scanning, should be available for patients taking aromatase inhibitors, and offered according to local guidelines. Treatment for drug induced bone loss, such as calcium supplementation and bisphosphonates where necessary, should also be available.

(c) Chemotherapy

Adjuvant chemotherapy prolongs disease-free and overall survival in patients with early breast cancer⁴⁰ especially in premenopausal women with ER negative tumours (Level 1 evidence). The efficacy of chemotherapy is greater in younger patients. Efficacy of chemotherapy is seen in both ER positive and negative breast cancer. However in ER positive disease treated by endocrine therapy the additional absolute benefit of chemotherapy should be calculated. This is particularly the case where the risk of recurrence is low, ER expression is high &/or the patient is of older age where they are competing causes of mortality.

(d) Targeted therapies

Trastuzumab (herceptin) is a monoclonal antibody to the HER2 receptor protein. In HER2 positive women, adjuvant trastuzumab (when combined with chemotherapy) approximately halves the risk of disease recurrence and death^{41,42} (Level 1 evidence). HER2 testing should be available for all new patients with invasive breast cancer; the test results must be available for discussion at the 'post operative results' MDT meeting. Trastuzumab should be offered to all suitable patients according to NICE guidance.⁴³ Cardiac monitoring, both pre-treatment and during treatment should be available, as trastuzumab can lead to cardiac toxicity.

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 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

SECTION 12: CLINICAL FOLLOW UP

Early diagnosis and adjuvant treatments have improved the outlook for many patients with breast cancer. However, a proportion of patients will still develop distant metastases and die of the disease. Two-thirds of all recurrences occur within the first 5 years after treatment, the frequency of events decreasing with time.

There is no firm evidence that early detection of local or systemic recurrence improves survival. However many breast cancer patients seek reassurance that they are free of recurrence and that any such recurrence will be detected at the earliest opportunity. The lack of survival benefit for clinical follow up has been documented in the "Recommended Breast Cancer Surveillance Guidelines" adopted by the American Society of Clinical Oncology (ASCO).¹³ Randomised studies testing the value of intensive follow up suggest that there is little or no survival benefit accruing from intensive surveillance with multiple investigations^{10,44–48} (Level 2 evidence). However the majority of these studies were carried out 10–20 years ago when many of the current new drug regimes were not available. Furthermore in many of the studies the follow up would not be regarded as intensive by today's standards.

A previous report by the National Institute for Clinical Excellence (NICE) recommends that routine hospital follow up is discontinued after three years unless patients are within clinical trials and that subsequent follow up should be maintained in the community with rapid access to the breast clinic via the Breast Care Nurses in cases of suspected recurrence.⁵ However the level of evidence for this recommendation (ie, discontinuing standard follow up) is low.

The Association of Breast Surgery at BASO has noted the above report and made the following recommendations:

- Patients on continuing active treatment should be followed up until such treatment has been completed.
- Patients with ER positive disease may need to be seen at planned intervals to discuss changes in therapy, the so called 'switch' or 'extended' therapy situations.
- Follow up should be stratified according to disease risk. Patients should be given information regarding their personal follow up programme (clinical and imaging).
- High risk patients may be followed up more closely with joint care by surgeons and oncologists according to agreed local protocols.
- Data about long-term follow up is essential in monitoring clinical outcomes – locally, regionally and nationally. Data collection must be reliable and functioning if hospital visits either occur or are omitted. Alternative means of data collection in the absence of hospital visits should be considered such as postal or primary care follow up. Resources for data collection, both I.T. and managerial, should be provided by the hospital in collaboration with primary care. All breast units should participate in ongoing national audits such as the NHSBSP/ABS at BASO audits, the BCCOM audit and the Sloane Project. Mortality data should distinguish between deaths due to breast cancer and deaths which are unrelated or where the cause is uncertain. There must be a nominated surgeon who is responsible for the accuracy of the data collected by the breast unit.
- Discharge of follow up to primary care should be an agreed and integrated process and subject to audit. Since most recurrences occur in the first 5 years and the most commonly used benchmarks for outcome in breast cancer are the 5 year recurrence or survival rate, it is recommended that patients should be followed up for 5 years but this period may vary with local and clinical trial protocols. Patients in clinical trials should continue to be followed up according to the trial protocol.
- The ideal frequency for mammographic follow up is not established and current practice is variable.⁴⁹ Current UK guidelines from the Royal College of Radiologists^{50,51} suggest routine mammography every 1–2 years for up to 10 years after diagnosis.
- If a GP detects a possible recurrence, the patient should be referred back to the breast unit and there should be a mechanism to facilitate this.
- Patients diagnosed and treated for breast cancer will have ongoing requirements to meet their psychosocial needs, surveillance of ongoing treatment effects, monitoring of primary treatment morbidity and monitoring of recurrence rates. All these aspects of care should be provided for in whatever follow up regime is proposed through local cancer networks.

There will remain a substantial hospital outpatient requirement for patients previously treated for breast cancer and this requirement will need to be resourced.

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 NHS Breast Screening Programme audits, the BCCOM audit and the Sloane Project

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Notes

Levels of evidence: evidence is graded 1 (derived from randomized controlled trials – RCTs), 2 (observational studies) and 3 (professional consensus). These are broad categories and the quality of evidence within each category varies widely. Thus it should not be assumed that RCT evidence (grade 1) is always more reliable than evidence from observational studies (grade 2).

These guidelines are advisory and will be reviewed in 2011.