The British Association of Surgical Oncology

GUIDELINES FOR SURGEONS IN THE MANAGEMENT OF SYMPTOMATIC BREAST DISEASE IN THE UNITED KINGDOM

(1998 Revision)

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The BASO Breast Speciality Group

FORWARD

The BASO Breast Group was formed out of the surgeons who were undertaking breast cancer screening. The group formed the National Surgical Coordination Group for Breast Cancer Screening, and in that role set quality assurance standards. These were published in 1992 as the 'Guidelines for Surgeons in Breast Cancer Screening' [1]. *These were the first national guidelines to be published on any surgical matter, and received praise from the National Audit Office. The establishment of National Standards had the beneficial effect of pushing Trusts to provide the time, beds, operating lists and back-up necessary for surgeons to meet them.*

Breast Surgery is not neatly compartmentalised into screening and symptomatic work, as in radiology. To us, a breast cancer is a woman requiring treatment, by whatever route the cancer came to light. The Screening Guidelines gave rise to the anomaly that we could quote quality standards for some of our patients with breast cancer to protect them from long waiting times and to ensure good diagnostic pathways, but could not do so for others.

The work of the BASO Breast Group has increasingly taken in all aspects of breast surgery: recommendations on training [2], *establishing education courses, a reconstruction subgroup, a legal subgroup. As part of this expanded role, the 'Guidelines for Surgeons in Symptomatic Breast Disease' were first produced in 1995* [3]. *The format of the Symptomatic Guidelines follows those of the Screening Guidelines: among general guidance a number of quality objectives are identified and outcome measures set for them. This process has essentially produced an audit programme, which has been computerised (with an educational grant from Zeneca Pharmaceuticals) as the BASO Breast Cancer Database. This will allow Breast Cancer Units to easily audit themselves, produce data on service delivery for inspection by purchasers, and record long-term outcomes.*

The uniform collection of data allows the production of national data. International interest has been expressed in the system, the Guidelines have been adapted by the European Society for Surgical Oncology [4], *and it will be a great achievement by BASO if the database is adopted worldwide.*

Our various Guidelines are now reviewed and updated every two years, and this edition is the first revision of the Symptomatic Guidelines. The initial editions of both the Screening and Symptomatic Guidelines were consensus-based. In line with the format used by the Clinical Outcomes Group in 'Guidelines for Purchasers Improving Outcomes in Breast Cancer' [5] *we have tried to make the guidelines more evidence-based. As in the previous Symptomatic Guidelines, the quality standards deal largely with service provision and diagnosis rather than case management. We will hope in the future to enter more into treatments as evidence unfolds from clinical trials (in part from our own trials BASO II on the small, well-differentiated tumours; BASO III, which will shortly be recruiting elderly women with breast cancer; Robert Mansel is in the process of establishing a BASO IV trial on Sentinel Node Biopsy).*

The thanks of the BASO Breast Group go to Hugh Bishop, our Honorary Secretary, for his constant direction and shepherding of all who contributed to the revision of these guidelines, and we are most grateful to Zeneca Pharmaceuticals and the Breast Cancer Campaign for educational grants, to aid publication.

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INTRODUCTION

These guidelines are concerned with the process of delivering high quality breast care to patients. This is a consensus document which is evidence based where appropriate. It must be recognised, however, that evidence is largely lacking for the process of care. For this reason these guidelines represent targets for clinical excellence which may not be immediately achievable.

THE BREAST UNIT

In 1994 the Chief Medical Officer published a Policy Framework for commissioning cancer services suggesting that the care of malignant disease be delivered through Cancer Centres and Cancer Units [6]. Subsequently, under the direction of Professor Haward, two documents were produced [5], which spelt out the evidence for delivering breast cancer services through specialised departments. The Cancer Units are visualised to be District General Hospital based and to manage the diagnosis and initial treatment of the common cancers in cancer site specific Units.

In the same vein, a report produced by the British Breast Group [7] calls for breast cancer to be managed by surgeons, radiologists, pathologists, clinical and medical oncologists and nurse specialists, each of whom specialises in breast cancer and working as a team. It should be emphasised that equivalent standards of care should be delivered in Cancer units as in Cancer Centres although facilities such as radiotherapy may not be available in Cancer Units .

The Breast Cancer Unit will usually be based in the District General Hospital. The calculations for expected patient numbers and the time commitment for specialist staff are shown on page 12. It is likely that most District General Hospitals will have a Breast Cancer Unit although where hospitals are close together it will be more cost-effective for one only to provide breast care.

The advice of the British Breast Group and of the present B.A.S.O. Guidelines for Surgeons is that breast cancer care in any one area of the community should be provided by breast specialists in each discipline, working as a team and providing services from early detection through to care of advanced disease.

The Role of the Surgeon

The primary care of breast cancer is currently the responsibility of surgeons and there is no evidence to suggest that a change in this practice would be beneficial. Approximately 25% of the outpatient surgical workload in a District General Hospital is related to breast disease [8]. There may be an advantage to having a breast disease directorate, or certainly a separately identified breast budget, which should include screening and care of patients with advanced disease.

The most common cancers are initially managed by surgeons and the provision of appropriate surgical specialists to manage patients in this phase of their illness, both for their diagnosis and for the performance of a major surgical resection, is essential [6]. The service within Cancer Units in district hospitals is in many ways surgically led and this is not likely to change in the foreseeable future.

Surgical sub-specialisation in the common cancer sites within the Cancer Unit is essential and a hospital should only seek to function as a Cancer Unit if the volume of work related to each cancer site is sufficient to maintain such sub-specialisation. The presence of appropriately trained site-specialised consultant surgeons in the Cancer Unit and the development of appropriate specialisation that will provide care for an adequate number of patients is fundamental. In future consultant surgeons who specialise in a particular anatomical area (site-specific surgeons) should carry out the surgical management of that cancer.

The surgeon has a central role in establishing and leading the Breast Unit as, apart from screening, the patient's first contact is likely to be with the surgeon. The surgeon also has responsibility for coordinating the multi-disciplinary team. Most of the work of a Breast Unit is outpatient based and much is what has been referred to as 'reassuring the worried well'. This considerable diagnostic workload has to be borne in mind when surgeons seek to define the number of sessions identified for breast disease.

The surgical speciality of Breast Disease is now established and the Senate of the Royal Colleges of Surgeons recognises the B.A.S.O. Breast Specialty Group. A patient should no longer be content with referral to any surgeon but should be able to attend a breast clinic where there is special expertise. Although much of this document relates to the management of women found to have breast cancer, benign breast disease is an important element in breast practice and should never be underestimated or underrated in terms of how the patient perceives it.

PRIMARY CARE SERVICES

In the UK referral to a surgeon is via a general practitioner (GP). It is essential that GPs establish links with Breast Units and are able to arrange urgent referral according to the agreed National Guidelines when required [9]. Contracts must include provision for communication to the GP of the diagnosis and proposed treatments (Table 1).

Access for mammography

- Direct access for GP-requested mammography is not recommended. Open access mammography should be unnecessary if access to a Breast Clinic is adequate.

The overall sensitivity of mammography on its own is about 83% but is considerably less in young patients [10]. A negative mammogram does not exclude cancer.

Mammography is a screening test and is not appropriate as the sole or initial diagnostic test for symptomatic breast disease. Diagnosis of a breast lesion is based on the three complementary aspects – clinical, imaging and cytology or core biopsy – often known as Triple Assessment . A mammogram is not required in all women with breast symptoms. Mammography alone does not exclude a breast cancer and (apart from screening) must be performed in conjunction with these other diagnostic modalities. It is seldom appreciated that even palpable breast cancers may not be visible on a mammogram, particularly in a young woman. Pre-operative mammography (with or without an Ultrasound examination) should be regarded as a prerequisite for the adequate assessment of patients with primary operable breast cancer. Even though the radiation dose used in mammography is low the technique is inappropriate under the age of 35 unless there are very special reasons; surgeons should follow the local radiological guidelines.

Hormone Replacement Therapy

- There is no evidence that women on Hormone Replacement Therapy (HRT) require more frequent mammograms than are received through the National Breast Screening Programme.

Screening for women under the age of 50.

- There is little evidence that women who are apparently of ordinary risk of breast cancer under the age of 50 benefit from screening mammography. This also applies to women who are placed on to HRT at this stage.

Family history of breast cancer

Many women enquiring about a family history of breast cancer will not have a significant history. There is also widespread public and professional misunderstanding of the likely impact of recent advances in the genetics of breast cancer and an unreasonable expectation that they will become readily available. The majority of breast cancers are not genetic and the importance of genetic factors has been overemphasised. There is also an assumption that identification of breast cancer gene mutations in an individual will result in a reduction in mortality. This is unproven.

Referral to a family history clinic provides an opportunity for risk assessment, counselling, and the opportunity to take part in screening or prevention studies and any other research programme.

The following is a potential management strategy for those women who present with breast symptoms or because of their concern about their family history.

Management of high risk group: The high risk group is defined as :

1. breast / ovarian families with four or more relatives on the same side of the family affected, at any age
2. breast cancer (only) families with three affected relatives with an average age at diagnosis of < age 40 years
3. breast / ovarian families with three affected relatives with an average age at diagnosis of breast cancer < age 60 years
4. families with one member with both breast and ovarian cancer

These patients should be referred to a specialist cancer genetic consultation at a regional genetic centre. Gene testing may be appropriate for some of these patients.

Management of moderate risk group: The moderate risk group includes those women with:

1. one first degree relative with breast cancer diagnosed under age 40
2. two first or second degree relatives with breast cancer diagnosed under age 60, or ovarian cancer at any age
3. three first or second degree relatives with breast or ovarian cancer diagnosed at any age
4. a first degree relative with bilateral cancer under age 60
5. a first degree male relative with breast cancer at any age

The relative risk of breast cancer for women in this group is at least three times that of the general population. Given the sparsity of evidence for intervention in this group it is recommended that patients should be managed within the context of clinical studies.

A possible age dependent screening protocol could be:

Below age 30	No mammography
Age 35 – 49	Annual mammography (consider screening from 5 years prior to age at diagnosis in relative if this is age <39)
Over age 50	Mammography every 18 months (i.e. additional mammogram between three yearly NHSBSP mammography)

Management of low risk group: The strategy for these women should be to discuss the difference between familial and non-familial cancer and to explain that that individual's risk is not significantly elevated. They should be informed that the risk of non-familial breast cancer (the most common type) remains and be encouraged to participate in the National Breast Screening Programme at an appropriate age.
It is essential that the advice offered to women is the same, whether in primary care, the Breast Unit or the regional Cancer Centre.

DIAGNOSTIC SERVICES

The breast diagnostic process should be carried out in a designated Breast Clinic. When close to a Breast Screening Assessment Unit it would seem logical to combine the two facilities (staff and equipment). Diagnosis should be based on Triple Assessment, when an initial clinical assessment may be followed by appropriate imaging, cytology and pathology as required.

- Women with significant breast symptoms or signs should be referred to a surgeon within the district with a specific interest and training in breast disease. The surgeon should work within a multi-disciplinary Breast Clinic, which must be properly staffed and equipped [7].

- The Breast Clinic should be structured to produce a rapid and multi-disciplinary assessment of the patient with breast disease. For the convenience of patients, diagnostic tests should be programmed to ensure the minimum number of visits.

- The majority of patients should receive all diagnostic tests at the first visit. They may then be told that there is no abnormality or that their lesion is likely to be benign, by the end of that appointment.

Communication

- Patients should be encouraged to bring a partner or friend with them when the results are being discussed.

- Breaking bad news should be done in a professional way. The person conducting the consultation must be a member of the multi-disciplinary breast team and should have the breast care nurse in attendance. It should take place in an appropriate environment with adequate privacy.

- The follow up arrangements should be clear. The patient must know how to contact the breast care nurse and the nurse must be aware of what her own plan is in terms of follow up.

Quality standards of diagnosis

Quality Assurance standards for the diagnosis of breast cancer include the following:

Administrative standards

It is appreciated by surgeons that any symptomatic breast referral may be a carcinoma and certainly may be a carcinoma in the mind of a patient. The purpose of seeing patients quickly is to provide reassurance as to the nature of the problem and to alleviate anxiety.

It is the responsibility of management to ensure there are adequate facilities and personnel to meet these standards.

Table 1
BREAST CLINIC

Quality objectives	Outcome measures
To ensure ease of referral to the Breast Unit	The breast unit must inform GPs of how patients can be referred for rapid assessment. This includes patients already under the care of the Breast Unit such as those with advanced disease
To ensure that urgent referrals are seen rapidly	More than 80% of patients, who subsequently prove to have breast cancer, should be seen within two weeks of receipt of the referral by the unit
To ensure appropriate assessment in the Breast Unit	Breast Units must establish multi-disciplinary clinics for assessment of new patient referrals
For women to be seen by breast specialists	The clinic should be served by staff specially trained in breast disease: surgeons, radiologists and radiographers, cytopathologists and breast care nurses
To ensure appropriate communication from the Breast Unit to the GP	More than 90% of GPs must receive appropriate information from the Breast Unit within one week of a patient's clinic appointment

Radiography, Imaging and Physics Standards

- Radiographers taking mammograms should hold the College of Radiographers Certificate of Competence in Mammography [11].

- Symptomatic mammography should only be carried out by designated radiographers with appropriate skills and knowledge. These radiographers should be seen as part of the breast diagnostic team.

- Where there is a Screening Unit the same radiographers should work in the symptomatic Breast Clinic. If the radiographers in the Breast Clinic are not involved in the

NHS Breast Screening Programme they should have audited standards equivalent to those which apply to radiographers in the NHS Breast Screening Programme and should establish links with Breast Screening Units, in order to share knowledge and awareness of current mammographic techniques.

Imaging and physics standards in a Breast Unit

These are essentially the remit of the radiologist who is a member of the breast diagnostic team.

- Physics services should meet the NHSBSP guidelines [12].
- Units should have in place a quality control programme to monitor and maintain standards [13,14].
- In order to achieve image quality of at least the minimum standards laid down for screening, the radiology service should optimise the quality obtained in their existing equipment including films, screens, cassettes and processors [12].
- Radiological equipment including mammography and ultrasound, when due for replacement, should be replaced by equipment meeting NHSBSP standards.

RADIOLOGY SERVICES

Breast imaging services

Breast imaging must be carried out and reported by a radiologist experienced in breast imaging and who satisfies the minimum standards set out in the guidelines for radiologists involved in the NHS Breast Screening Programme [15]. The radiologist is an integral member of the breast diagnostic team and must work closely with the breast surgeon, pathologist and oncologist. The surgeon and radiologist must consult together regularly and preferably work together in the diagnostic breast clinic.

Radiology Standards

- Professional standards for radiologists are defined in the Quality Assurance guidelines for radiologists [15]. Radiologists involved in breast imaging must meet these standards.
- Mammography equipment which is suitable for magnification and localisation procedures must be available.
- Ultrasound equipment suitable for breast examination must be available.
- Reports of imaging examinations should include details of the site, size (in millimetres), extent and nature of any abnormality, a description of any significant associated features with an opinion as to the most likely diagnosis (i.e. R2 – R5).
- Radiologists should participate in the multi-disciplinary review of the results of imaging as part of diagnosis and should participate in regular audit of their individual performance.
- Radiologists involved in primary diagnosis should also, where possible, participate in the imaging of patients following treatment and be familiar with breast treatment imaging changes and their clinical relevance. Guidance on the use of imaging in the follow up of patients with breast cancer has been published by the Royal College of Radiologists [16]
- The radiologist should also be involved in decisions on the most appropriate imaging investigations.

Table 2
DIAGNOSIS

Quality objectives	Outcome measures
To minimise the number of outpatient visits for diagnostic purposes	If imaging and/or cytology or core biopsy are required they should be performed at the initial visit <10% of all new breast patients should be required to attend the clinic on more than two occasions for diagnostic purposes
To ensure that patients attending for diagnostic purposes are seen by a breast specialist	Patients attending for diagnostic purposes should be seen on at least one occasion by a breast specialist (consultant surgeon, clinical assistant or associate specialist with special training in breast disease). Higher surgical trainees should only give unsupervised opinions in breast diagnostic clinics when judged competent to do so by the supervising consultant
To minimise patient anxiety between a surgical decision to operate for diagnostic purposes and the first offered admission date	>90% patients should be admitted for an operation within two weeks of the surgical decision to operate for diagnostic purposes
To produce an adequate FNA sample that can be incorporated into the Triple Assessment process	The overall inadequate cytology (C 1) rate should be < 20% for all new patients undergoing triple assessment
To make a preoperative cytological or core biopsy diagnosis in breast cancer patients	> 90% of patients subsequently proven to have breast cancer should have a preoperative FNA (C5) or core biopsy (B5) that is diagnostic of cancer

PATHOLOGY SERVICES

The Breast Team must include a pathologist or pathologists with special expertise in breast pathology and cytology, with designated time for breast cancer work. The pathology services should be organised according to the NHSBSP guidelines and with the pathologist in the same multi-disciplinary team [17].

Cytology and Core Biopsy standards

- The report of fine needle aspiration cytology and core biopsy specimens should follow the format used by the NHS Breast Screening Programme. Results of cytology specimens are categorised as either:

  C1 = inadequate
  C2 = benign
  C3 = atypia probably benign
  C4 = suspicious of malignancy
  C5 = malignant

as in the 'Guidelines for Cytology Procedures and Reporting' in Breast Cancer Screening [18].

Histopathology standards

Histopathology procedures and reporting should be as described in the NHSBSP document 'Pathology Reporting in Breast Cancer Screening' [17]. The recording of data for symptomatic patients must be the same as that for screen detected patients.

In particular the following points are extracted from the guidelines:

Managerial

- Histopathology departments and surgeons must have access to specimen radiography .
- Histopathology laboratories must be accredited.

Reporting.

Histopathology reports should include information on the following factors:

- The maximum diameter of carcinomas should be measured in millimetres (mm) and the extent of intraductal and invasive disease recorded in the report.
- The report should comment on the extent of disease and whether the tumour contains an extensive insitu component. This is achieved by giving 2 measurements for invasive carcinomas where ductal (but not lobular) carcinoma insitu extends to more than 1 mm beyond the invasive component:

  1. the size of the invasive component
  2. size of the whole tumour

  Tumours identified as multicentric should be so reported.
- The pathologist must report on the distance of surgical excision margins and this should be discussed at the multi-disciplinary meeting. An adequate margin may be defined as that margin which ensures a local recurrence rate in the conserved breast of less than 5% at five years.
- Surgeons are reminded that such a report cannot be given unless the surgeon clearly orientates and marks the specimen prior to delivery to the pathologist. The Breast Care Unit must have a clear protocol for the handling of pathological specimens.
- Subtyping of invasive and insitu cancers must use standard nomenclature as recommended by the NHS Breast Screening Programme in the pathology guidelines [19].
- Histological grading of cancers must be undertaken using the method described by the pathology guidelines. Results must be incorporated into the report.
- Sufficient lymph nodes must be examined to satisfy the requirements of local treatment protocols.
- The presence or absence of lymphovascular invasion must be stated.
- Tumour receptor status must be determined where local treatment protocols require it.

TREATMENT PLANNING

Treatment of the primary tumour must follow written protocols agreed by the Breast Team.

Following diagnosis, women 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 and the decisions agreed with the patient must be recorded. In the event of a patient refusing the treatment options recommended this should also be recorded. (Table 3)

Table 3
MANAGEMENT PROTOCOL

Quality objectives	Outcome measures
Treatment of breast cancer should be managed by staff with special training and expertise in breast disease	Every Breast Unit must have a written protocol for the management of breast disease

Close communication must be maintained between surgeons and the clinical or medical oncologists to plan primary treatment and facilitate subsequent adjuvant therapy. A care plan for each woman must be drawn up. Considerations in framing this must take account of factors predictive of both survival (lymph node status, Nottingham Prognostic Index) and of local or regional recurrence, the age and general health of the patient, social circumstances and patient preferences [20]. Planning should also allow for the availability of reconstructive surgery for those women who wish to consider this.

SURGERY

Surgical treatment of breast disease must be carried out by surgeons with a special interest and training in breast disease. Breast surgeons should work in Breast Teams which have the necessary expertise and facilities for a multi-disciplinary approach.

All patients should have the opportunity to receive advice on reconstructive breast surgery where appropriate. 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. There should be adequate facilities for: outpatients, inpatients, day patients and theatre sessions.

Secretarial support

A breast practice generates a large administrative workload (clinic appointments, operations, etc.) and it is essential that the breast team has adequate clerical support.

Data Management

The Breast Unit requires adequate resources in terms of Information Technology and data processing in order to collect patient data prospectively.

Multi-disciplinary case review and planning

Consultants within the breast unit (Surgery, Radiology, Pathology and Oncology) must have contractual time for attendance at the multi-disciplinary meeting. It is mandatory for trainees within breast surgery and its related disciplines and also the breast care nurses to attend the multi-disciplinary meeting. A record of attendance will be kept in a diary and also in trainees' logbooks. (Table 4)

Table 4
MULTI-DISCIPLINARY MEETINGS

Quality objectives	Outcome measures
Multi-disciplinary discussion of patients undergoing treatment for primary breast cancer	A multi-disciplinary meeting should take place on a weekly basis to consider the clinical, radiological and pathological results of cases recently operated upon and to discuss the results of triple assessment. A record of the meeting, including the attendance, should be kept and conclusions documented in the patients' notes

Avoidance of delay in 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. Where the operation is being carried out to establish the diagnosis (i.e. to confirm or exclude malignancy) or for therapeutic purposes following a proven diagnosis of cancer, the operation is classified as 'Urgent'. These are urgent rather than emergency operations but nevertheless are associated with a great deal of anxiety by the patient. It is good practice for an operation for diagnostic purposes to be within two weeks of the decision to operate, and an initial therapeutic operation to be within three weeks of the decision to operate. The maximum acceptable wait for therapeutic surgery should be four weeks, except where treatment is planned to be delayed. There is no biological evidence, however, that a delay of four weeks has any effect on survival. Resources must be available to achieve these targets. (Table 5)

Table 5
SURGERY

Quality objectives	Outcome measures
To minimise surgical morbidity for impalpable lesions	>90% of diagnostic biopsies on impalpable lesions which subsequently prove benign should weigh less than 20 g. The Surgeon should ensure that the weight is recorded either in theatre or by the Pathologist
To reduce the number of open surgical diagnostic operations	The Benign-Malignant operation rate (this is the ratio of open surgical biopsies which prove benign to the total number of breast cancers diagnosed on the Unit) should be no more than 1 : 10. (Operations for nipple discharge, abscesses and excision of previously diagnosed fibroadenomata should not be included)
To minimise patient anxiety between a decision that a therapeutic operation is required for cancer and the date for operation	>90% of patients should be admitted for the first therapeutic operation within three weeks of informing the patient of the need for surgical treatment. Resources must be available to achieve this

Surgical procedures

Some breast operations are suitable for day case surgery but this is not always so. There must be recognition of the emotional needs and general health of the woman. The decision as to whether day case surgery is appropriate should be made on an individual basis by the surgeon and not dictated by a general management policy laid down by the purchasers or the provider unit.

All diagnostic biopsy specimens should be weighed by the surgeon or pathologist. More than 90% of diagnostic biopsies for impalpable lesions which subsequently prove to be benign should weigh less than 20g in line with the current Quality Assurance Guidelines for breast cancer screening. This target weight is arbitrary but data from the 1996/97 audit of screen detected breast cancer confirms that the median weight achieved by surgeons in the U.K. was 20g. Although controversial it is recommended that, for the time being, this target be maintained.

Perioperative investigations

There is good evidence that a perioperative search for occult metastases (e.g. bone scan, liver ultrasound) does not yield useful information in a woman with operable primary breast cancer [21]. These investigations should not be carried out unless the patient is symptomatic. These investigations are, however, essential for the investigation of symptoms in the follow up clinic [22].

Surgery for primary operable breast cancer

Table 6
SURGERY 2

Quality objectives	Outcome measures
To ensure completeness of excision in breast conservation	Patients with involved circumferential margins should not proceed to further adjuvant therapy without having a further surgical excision as defined by local protocol. An adequate surgical margin may be defined as that which results in a local recurrence rate of less than 5% at 5 years, in the conserved breast
To minimise the number of therapeutic operations in women undergoing conservation surgery	The number of operations should be recorded. >90% of women having conservation surgery should have three or less therapeutic operations
To ensure that all necessary data is obtained for making decisions on adjuvant radiotherapy or other systemic therapies	Histological node status should have been obtained in 90% of invasive tumours in women having a planned curative operation. Where node sampling has been undertaken a minimum of 4 lymph nodes should have been obtained in 90% of cases
To ensure the appropriate treatment of ductal carcinoma insitu (DCIS) in the absence of invasive breast cancer	A local excision is not appropriate for extensive or multi-focal DCIS. Patients with previously diagnosed DCIS should not undergo an axillary clearance

Perioperative and follow up care

Patients should be supported by a clinical nurse specialist (breast care nurse), who is a member of the Breast Team and who should have established links with the ward nurses to assist in continuity of care. Following initial surgery, 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 provided with literature to take home, including details of further follow up treatment and information about local self help support groups. It is desirable that support groups should only work with patients under the direction of the breast care nurse.

Communication with General Practitioners

The Breast Team should ensure that GPs receive communications that give them a clear understanding of the diagnosis, care plan, and toxicity profile of any proposed systemic treatment. Such communications must be sent after the first postoperative review and following any subsequent change of any treatment. It is the responsibility of clinical trialists to ensure that GPs are fully briefed about any trial that the patient is entering and any potential side effects.

Standards and Audit

Breast Units should be in a position to provide data on the number of patients treated and type of treatment received. Units should also be able to report the long-term outcome measures in treating women with breast cancer (the BASO v2.0 database software is currently available to facilitate this). This will include data on local and regional recurrence, long term morbidity of the primary treatment such as lymphoedema, uncontrolled local recurrence, distant metastases and death. There must be a nominated surgeon who may delegate this task but who is ultimately responsible for the accuracy of the data collected by the Breast Unit.

The BASO minimum data subset will be available on the BASO Breast Specialty Group internet web site. (http://www.BASO.org)

Table 7
QUALITY ASSURANCE

Quality Objective	Outcome Measure
The BASO minimum data subset should be available for external Quality Assurance	The surgeon or lead clinician of the Breast Unit must have overall responsibility for production of the above data by the Unit . It is the responsibility of management in each unit to ensure that adequate resources are available for this

The Breast Surgeon should ensure that data on diagnosis and treatment of breast disease is recorded . Each Unit must be able to provide results of its audit of surgical data for purchasers on at least an annual basis. The BASO Breast Specialty Group will endeavour to ensure comparability of these data (Table 7).

THE BREAST CARE NURSE

The breast care nurse is part of the Breast Care Team and should be available for all patients undergoing treatment for breast disease [23] (Table 8).

Table 8
BREAST CARE NURSE

Quality objectives	Outcome measures
All patients diagnosed with breast cancer should have access to a breast care nurse	All women with breast cancer must be given the opportunity to see a breast care nurse pre-operatively

The breast care nurse should be present, particularly at the time of diagnosis, when any options for treatment are discussed. A suitable room with adequate privacy should be available at this time. The patient may be emotionally shocked and may not take in everything that she is told and the presence of a companion such as a husband or friend is often helpful. A telephone contact number and/or further appointment may be made to discuss treatment again and answer any questions. Women with benign conditions must also be given the opportunity to have questions answered and be given information.

The nurse should be available to see patients pre- and post-operatively on the ward, where such matters as arm exercises and operative complications worrying the patient, can be discussed together with any personal problems. Temporary prostheses may be fitted by the nurse before discharge and booklets given regarding treatment, hospital support groups, etc. Support must be available on subsequent visits to outpatients when women may be receiving their results and further treatment may be discussed. The patients should be offered

advice on bras, swimwear and choice of permanent prostheses where appropriate. Following axillary surgery and/or radiotherapy all patients should be advised on care of their arm. Following surgery for breast cancer, all patients must be observed for signs of anxiety and depression and referred, when appropriate, to specialist psychiatric help.

The nurse should keep herself up-to-date with knowledge of breast disease; taking part in research helps this but there must be an agreed programme of continuing education. She needs to be involved in the education of nursing staff on breast disease, both in the hospital setting and elsewhere.

Ideally Breast Units need two breast care nurses and it is mandatory that these nurses attend the multi-disciplinary breast meeting.

MANAGEMENT OF RECURRENT DISEASE

Clinical Follow-up

Although early diagnosis and new modality treatments have improved the outlook for many woman with breast cancer, approximately 60% will have some form of recurrence and one half of all patients will eventually present with distant metastases and die of the disease. An estimate of survival in the individual woman with breast cancer can be predicted using simple methods of prognostic scoring, e.g. lymph node status, Nottingham Prognostic Index at the time of initial treatment [20]. Two-thirds of all recurrences occur within the first 5 years after treatment, the incidence of events decreasing exponentially with time (Table 9).

Table 9
LOCAL RECURRENCE

Quality objectives	Outcome measures
To ensure the early and accurate diagnosis of local recurrence	The surgeon must ensure that adequate follow-up is provided as defined by the Unit protocol. The surgical team must be involved in the follow-up of patients treated with breast conservation
To minimise the development of local recurrence in the conserved breast	<5% of patients should develop local recurrence in the conserved breast within 5 years
Following the treatment of a primary tumour, patients should have easy access to the Breast Team at any time	Patients should receive written information on how to contact the breast care team (which may be through the Breast Care Nurse)
To ensure rapid diagnosis of recurrent or metastatic disease	Written guidelines on the management of recurrence (local, regional and distant) must be available to all staff in the follow-up clinic
To minimise the development of local recurrence after mastectomy	< 5% of patients with primary operable breast cancer should develop local recurrence within 5 years following mastectomy

Local recurrence within the conserved treated breast

- Local recurrence is defined as further breast cancer within the skin or parenchyma of the treated breast (whether considered a recurrence or a new primary tumour).
- The Unit protocol must include indications and contraindications for conservation therapy.
- The detection of local recurrence following conservation surgery presents the same problems as the detection of a primary breast cancer. It should therefore be the responsibility of the surgeon, and follow-up should be conducted in a breast follow-up clinic by the surgical team with the cooperation of other members of the diagnostic breast team, working to standards that are the same for the diagnosis of primary breast cancer. Although the clinical oncologist has joint responsibility with the surgeon for patients who have received radiotherapy it is inappropriate for patients treated by conservation surgery to be followed up solely by the Clinical Oncologst.
- The optimum frequency of clinical follow-up is not established and a recent survey demonstrates considerable variation in practice throughout England and Wales [24]. It is suggested that the patient be followed up on a regular basis for at least 5 years. The purpose of follow-up is to provide psychological support (especially in the first year) and to detect loco-regional recurrence or distant metastases.
- The ideal frequency for mammographic follow-up is not established and current practice is variable [24]. Surgeons are encouraged in future to enter patients into clinical trials assessing the optimal timing of mammographic follow-up.
- The follow-up of patients after treatment for breast cancer is an integral part of the management of breast cancer and appropriate facilities must be available.

Local recurrence following mastectomy

The advantage of follow up by the Breast Team is that local recurrence in mastectomy flaps may on occasion be difficult to recognise, as for example, when it presents as an eczematous appearance of the flaps. Distant recurrence may also present clinical dilemmas (for example hypercalcaemia, endobronchial disease, lymphangitis of the lung, bone pain) and these are most likely to be recognised and appropriately treated by a specialist regularly dealing in breast cancer. The GP, it must be appreciated, will see on average only one new patient with metastatic disease from breast cancer every 3-4 years.

- It is suggested that patients should be seen at regular intervals for at least the first 5 years after mastectomy. However, cases at high risk of developing distant, local or regional recurrence should be seen at more frequent intervals. Such patients should be identified from the prognostic factors available and more frequent follow-up arranged for them.
- All women who have undergone treatment for primary breast cancer, whether regularly followed up or not, should have open access to a follow-up clinic, should they have concerns.

- If a GP detects the possibility of a recurrence, referral should, wherever possible, be back to the Breast Unit and not to another clinician. This implies that there must be a clear mechanism for the GP to contact the Breast Unit when problems arise.

Contralateral primary breast cancer

Previous breast cancer increases the risk of a contralateral second cancer fourfold. Women who develop their first cancer below the age of 40 may be at much higher risk.

- The optimal timing of mammography of the contralateral breast is currently unknown.

- The use of Tamoxifen decreases the incidence of contralateral breast cancer and may slow the appearance of the second primary breast cancer.

Surgical treatment of recurrent and locally advanced breast cancer

The breast care surgeon should be able to advise on reconstructive techniques in managing these conditions and may have personal operative experience. If the breast specialist does not have the prerequisite experience the Breast Unit must work in collaboration with a plastic surgeon with a breast interest.

Local relapse within the conservatively treated breast

Local relapse will usually be managed by mastectomy.

Local recurrence after mastectomy

The incidence of local recurrence in mastectomy flaps is influenced by the extent of the operation and by the use of radiotherapy. Local recurrence presenting as a single lesion within the flap may be treated by simple excision. More extensive recurrence such as dermal lymphatic invasion reflects the aggressive nature of the breast cancer and should be managed by a combined approach from the surgeon and clinical oncologist in a Combined Breast Clinic.

Treatment of a regional recurrence

Regional recurrence is a reflection both of primary treatment failure and the natural aggression of the disease. The majority of women with breast cancer do not develop symptomatic regional recurrence and it is therefore necessary to identify women at low risk of regional recurrence who need not be subjected to inappropriate axillary clearance or prophylactic radiotherapy. Most women with histologically involved nodes following axillary node sampling should have radiotherapy unless they have had an axillary clearance.

Locally advanced primary breast cancer

The treatment of locally advanced primary breast cancer must be the result of a consultation between the surgeon and the clinical or medical oncologist on the Breast Care Team. The patient should be managed in a Combined Breast Clinic. Overall survival is poor in this group of women although some improvement may be achieved by systemic therapy. Local control may usually be gained by a combination of treatments; radical surgery (sometimes including myocutaneous flaps or grafting procedures) and/or radiotherapy and systemic treatment. Achievement of local control of disease and symptomatic relief is of great importance.

The Management of Metastatic Disease

Following the symptomatic presentation of distant metastases, average life expectancy is around 2 years, with virtually all patients ultimately dying from breast cancer. The aim of treatment during this time is to palliate symptoms and to maintain the highest possible quality of life. Systemic treatments (endocrine or cytotoxic) give some prolongation of life in many patients and a substantial prolongation in some. A variety of treatments may be appropriate depending on the site of metastases, the likely benefit versus toxicity and the preferences of the patient. These include systemic anticancer therapies, palliative measures such as radiotherapy for bone metastases, and bone stabilisation by orthopaedic surgery (see 'BASO Guidelines for the Management of Bony Metastases').

The conclusion of the British Breast Group document is that, with the exception of having to receive radiotherapy, the proper care of patients with breast cancer should be centred at a Breast Unit [7]. This implies that patients should not be followed up in the Cancer Centre but should simply receive their radiotherapy there and then return to their local Unit for further follow-up clinics or for any other necessary therapies.

A patient with recurrent breast cancer should remain under the care of the Breast Unit. Treatment must be according to protocols agreed within the Breast Care Team. A specialist surgeon not only treats primary breast cancer but also is available to help in the management of women with advanced disease. However, as the disease progresses the focus of care shifts to a more predominant role for the non-surgical oncologists within the Breast Care Team. The majority of the treatment and all clinical assessment should take place in the Cancer Unit, rather than the Cancer Centre.

A patient with metastatic breast cancer requires considerable supportive care which may include relief of symptoms such as nausea and pain but must also acknowledge the patient's psychological, social and spiritual well being. The involvement of palliative care teams in the Hospital and the community should be sought.

The surgeon should have a good understanding of the natural history of breast disease and should be prepared to take a joint role with the oncologists in the Breast Team when assessing patients with recurrent disease.

RADIOTHERAPY, ENDOCRINE THERAPY AND CHEMOTHERAPY

- Radiotherapy and chemotherapy should be carried out by clinical or medical oncologists who have opted to specialise in breast cancer. They should have special training and interest in breast cancer and be active members of the Breast Care Team. The clinical oncologist will have experience in the use of radiotherapy in breast cancer and both the clinical and medical oncologists in the use of systemic treatments for breast cancer and the relief of symptoms associated with metastatic breast disease.

- It is probable that outcomes are better if treatment is prescribed and supervised by a clinical or medical oncologist with an interest in breast cancer.

Place of treatment

Treatment should be provided at the Breast Unit whenever practicable. Radiotherapy has to be provided at a Cancer Centre but the patient should be cared for at the centre by the clinical oncologist from her own Breast Team. Standard chemotherapy should be carried out at the Breast Unit but must be in a designated area that complies with the requirements for the safe handling of cytotoxic drugs and with adequate trained supervision.

Ongoing care in advanced disease

- Clinic attendances to assess progress should be at the Breast Unit and not at the Cancer Centre in order to ensure continuity of care by one team and to minimise travel problems

- This should be supported by a clinical nurse specialist (see section on the breast care nurse above).

Radiotherapy

In the case of patients with early breast cancer treated by wide local excision and postoperative radiotherapy, the time interval between the two should not exceed four weeks (except for clinical reasons) [25]. The precise time should be determined by clinical assessment and should take into account any time needed for wound healing.

Patients should be seen in a combined clinic by surgeon and clinical oncologist.

Where treatment requires both radiotherapy and chemotherapy, phasing of the treatments is decided for clinical reasons and the planned intervals should be strictly adhered to (Table 10).

Table 10
RADIOTHERAPY

Quality objectives	Outcome measures
To avoid inappropriate adjuvant radiotherapy	Prophylactic axillary radiotherapy is inappropriate in patients in whom an adequate number of lymph nodes has been examined by the pathologist to conclude that the patient is histologically node negative. No patient with DCIS (in the absence of invasive cancer) should have radiotherapy to the axilla
To minimise the development of local recurrence after mastectomy	There should be a written protocol that identifies those patients at high risk of flap recurrence who may require prophylactic radiotherapy to the chest wall
To reduce the incidence of axillary recurrence	Axillary recurrence needing further surgery or radiotherapy should be <5% at 5 years

Radiotherapy techniques

The clinical oncologist who is a member of the Breast Team should see the majority of breast cancer patients from that unit and should direct radiotherapy techniques.

Therapeutic radiographers should be appropriately trained, and staffing should be as recommended by the College of Radiographers for the safe use of megavoltage machines [26].

Patients should be reviewed by the clinical oncologist regularly throughout their radiation therapy.

Endocrine therapy

The overall benefits achievable in cancers responsive to endocrine manipulation may exceed any gains from cytotoxic therapy. This must be remembered when treatments are allocated for advanced breast cancer.

Endocrine treatments were historically ablative and the surgeon has therefore traditionally been associated with their application. The strategy developed within the breast team may still allocate the role of management of endocrine treatments to the surgeon, within the combined breast clinic.

- Where local protocols for adjuvant or advanced systemic therapies depend upon tumour Hormone Receptor content, this result must be made available to the Breast Team.

Chemotherapy

In cases in which adjuvant chemotherapy is required, the time interval between the decision to give chemotherapy and the start of chemotherapy itself should not exceed 3 weeks. Local protocols may vary this if radiotherapy is being given before chemotherapy. These target times include any waiting time for ward or hostel accommodation.

Delivery

Cytotoxic chemotherapy should be carried out under the supervision of an oncologist who is a member of the Breast Care Team and treating the majority of patients from that Unit. The effective delivery of these regimens requires the presence of a doctor or specialist nurse capable of intravenous cannulation and treatment, working under the clinical supervision of a consultant with special expertise in anticancer drug therapy in breast cancer. There should be adequate pharmacy support. There must also be adequate facilities and medical cover for the management of any complications which may arise. Patients and staff must be aware of, and GPs must be given full details of, how to access this cover.

Palliative and Terminal Care

Centres offering breast cancer treatment should ensure that there are adequate terminal care facilities to support the primary care team.

AN ESTIMATE OF THE SURGICAL WORKLOAD IN A BREAST UNIT

This estimate is for the surgical workload in a Breast Unit in a District General Hospital which covers a population of 300,000.

Once a Breast Unit is established it is likely to attract at least 90% of all breast referrals. Some 40 new breast symptomatic referrals will be seen each week which, together with the screen-detected cases, will generate between 180 and 250 new cancers per annum. Not all the patients will require surgery, due to factors such as age or advanced stage, but at least two cases per week will require standard primary breast cancer surgery. Some cases will require lengthier procedures, e.g. for extensive local disease or reconstruction. Added to this there are cases of loco-regional recurrence, mammographic lesions for diagnostic biopsy and benign breast conditions causing symptoms requiring surgery (such as mammary fistula). This caseload will require the input of two consultant surgeons with an interest in breast disease working as a team and contributing to the local breast screening unit. It will require a minimum of three operating lists per week. The total number of surgical sessions to be carried out by a specialist trained in breast disease is estimated below. These sessions should be carried out by trained specialists (at consultant or associate specialist level) or by advanced trainees (see Table 2).

Fixed sessions

- To see 40 new breast referrals per week, Units must hold at least one new Breast Referral Clinic per week seeing new patients and also those in whom a final diagnosis was not made at the previous visit. This will require two sessions of surgical time per week. Sessions should be held in a clinic with appropriate facilities such as mammography and ultrasound and with the presence of the radiologist on the Breast Team.

- *Three operating lists* for Breast Surgery.

- Primary breast cancer follow-up clinic for follow-up until disease becomes recurrent or advanced. This clinic is likely to be large and to require extra support which should not depend upon the surgical trainee. The consultant surgeon needs to be available for consultation (= *one session* of surgical time).

- One Screening Assessment Clinic held weekly. This Screening Assessment Clinic session should include a screening meeting (attended by surgeon, radiologist and pathologist from the breast team). Up to 20 cases are likely to be seen in one Assessment Clinic = *One Surgical Session*

- Combined Breast Clinic held weekly. Attended by consultant surgeon in addition to the clinical or medical oncologist on the Breast Team. Patients with distant metastases, locally advanced primary breast cancer or locally or regionally recurrent breast cancer will be seen in this clinic. Much of the work will be the province of the non-surgical oncologist(s) but the surgeon should be available for consultation (= *one half session* per week).

Sessional time to explain, with the help of the breast care nurse, the diagnosis of cancer and the treatments to be employed ('Results' clinic = *one half session* per week).

Continuing care = *one surgical session.*

Multi-disciplinary Breast Meeting = *one half session.*

The overall fixed surgical sessional commitment is thus *10 breast sessions made up of 6 to 7 clinic sessions and 3 operating sessions.* This means that two breast specialist surgeons (consultant or associate specialist) will be required per breast unit, each with four fixed sessions in breast disease and two in elective general surgery.

Note that these estimates are based on a Unit working with a population of 300,000 and in association with a Breast Screening Unit. Adjustments to the number of surgical sessions required should be made according to the size of the population covered and when the unit is not involved in breast screening.

Training and Continuing Education

The training of all general surgeons requires a level of competency in breast disease indicated in the Curriculum published by the Joint Committee on Higher Surgical Training [27]. A minority of trainees in general surgery will require sub-specialty training but if a trainee is to progress to an interest in the sub-specialty he or she will need to have had some exposure to breast disease. It is therefore recommended that all Higher Surgical Trainees should have some supervised outpatient exposure and operative experience in breast disease. The breast surgeon will also have the opportunity and responsibility to train surgeons who do wish to have a sub-specialty interest or who may require advanced training in breast surgery. It is important that such trainees are given graded responsibility, commensurate with their experience and skill and that they are given the opportunity for research into breast disease [28].

Personnel in Breast Units must be given sufficient encouragement and time to update their knowledge and skills. It is likely that in the future, postgraduate and continuing education in breast disease will be measured on a points system similar to

the system that is being set up by the Royal College of Radiologists. The BASO Breast Specialty Group will allocate points upon inspection of the programmes, symposia and specific training courses directed at breast disease. The meeting's secretary of the BASO Breast Specialty Group has already arranged annual study days for surgeons in breast disease and will continue to do so.

Research

Breast Units are encouraged to support clinical research and are expected to at least participate in multicentre studies aimed at improving treatments for breast cancer (Table 11). They should provide a record of any involvement.
There is evidence to suggest that patients treated in centres actively involved in research have improved outcomes [29]

Table 11
CLINICAL TRIALS

Quality objectives	Outcome measures
To encourage the entry of patients into clinical trials	The numbers of patients entered into ethically approved clinical trials should be recorded by each Breast Unit

Notes

These Guidelines are advisory. They will be reviewed regularly and amended in the light of experience gained. The next review will take place in the year 2000.

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