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Guidelines for the management of symptomatic breast disease

The Association of Breast Surgery @ BASO, Royal College of Surgeons of England

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Breast disease; breast cancer; Guidelines

Introduction

The publication of the first widely disseminated guidelines for surgeons on the management of breast cancer in the UK in 1992 followed the introduction of the national health service breast screening programme in 1987.[1] Subsequently guidelines in the management of symptomatic breast disease were published in 1995.[2,3] The breast group at BASO (now the association of breast surgery at BASO) was closely involved in the initiation and drafting of both documents.

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 units[4] 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. The breast cancer unit will usually be based in the District General Hospital but where hospitals are adjacent it may be more cost-effective for only one to provide breast care. 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.[5] In 2002, the National Institute of Clinical Excellence produced updated guidelines on improving the outcomes for patients with breast cancer.[6]

The advice of the association of breast surgery at BASO is that breast cancer care should be provided by breast specialists in each discipline. They should work as a team and provide services from the early detection of breast cancer through to the care of patients with advanced disease.

The breast unit

The breast multidisciplinary team

It is now widely accepted that multidisciplinary teams (MDT) form the basis for best practice in the management of breast disease. The vast majority of patients attending with breast problems have benign conditions or variations of normality. The constituent members of the breast team may be conveniently divided into two separate but interdependent 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

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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 of associate specialists, breast clinicians, staff grade surgeons and specialist registrar trainees.
- Specialist radiologist and radiographer
- Pathologist (cytopathologist and/or histopathologist) and laboratory support staff
- Breast care nurse
- Clinic staff
- Administrative staff

Cancer treatment team
This may include members of the diagnostic team as well as the following:

- Clinical oncologist
  Normally, a consultant clinical oncologist with a special interest in breast disease.
- Medical oncologist
  Normally, a consultant medical oncologist.
- Plastic and reconstructive surgeon
- Medical geneticist
- Data management personnel
- Research nurse
- Lymphoedema specialist
- Medical prosthetist
- Clinical psychologist
- Palliative care team

The role of the surgeon

The primary care of patients with breast cancer is currently the responsibility of surgeons.

Surgical subspecialisation for the common cancer sites within the cancer unit is desirable[7–9] (Level 3 evidence). 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 expertise. In general, consultant surgeons who specialise in a particular anatomical area (site-specific surgeons) should carry out the surgical management of that cancer. Retrospective data from the UK suggest that a minimum caseload of at least 30 newly diagnosed breast cancer cases per consultant per year is required to optimise patient outcomes[7] (Level 3 evidence). All surgeons involved in the management of breast cancer should be fully involved in MDT meetings.

Excessive surgical caseload is also likely to be detrimental. The association of breast surgery at BASO suggests that individual surgeons should ordinarily have a caseload of between 30 and 150 new patients with breast cancer per year (Level 3 evidence).

Recommendation (Table 4)
Only surgeons with a special interest in breast disease should treat patients with breast cancer and breast disease (Level 3 evidence).

Consultant surgeons should have a minimum caseload of 30 new breast cancer patients per year on average and ordinarily a maximum of 150 new cases per year (Level 3 evidence). Exceptions may include surgeons practising in geographical isolation.

An estimate of the surgical workload in a breast unit

The estimate for the surgical workload in a breast unit of a District General Hospital in association with a breast screening unit is based on a catchment population of 300,000. The current median for a DGH in the UK is circa 250,000.

A breast unit should attract all breast disease referrals and some 40 new symptomatic breast referrals will be seen each week. Together with the screen-detected cases, this will generate between 180 and 200 new breast cancer patients per annum. Not all patients with breast cancer will require surgery, but 3–5 cases per week will require standard primary breast cancer surgery. Some cases will require lengthier procedures for reconstruction or resection of extensive local disease. Loco-regional recurrence, mammographic lesions for diagnostic biopsy and benign breast conditions causing symptoms such as a mammary fistula, also require surgery. This caseload will require the input of two and possibly three consultant surgeons with an interest in breast disease working as a team. This will require a minimum of four operating lists per week but units performing breast reconstruction will require considerably more operating time. 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 or by advanced trainees under supervision.

Weekly fixed sessions

- In order to see 40 new referrals per week, units will need dedicated new patient clinic facilities. Twenty minute appointments for each new referral will require approximately four clinician

Table 1 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 properly trained breast care nurse pre-operatively and after discussion of histological findings

sessions (e.g. two consultant surgeons +2 other specialists including nurse practitioners) plus four breast imaging sessions (e.g. two consultant radiologists +2 radiographer advanced practitioners). The above clinician/imaging specialist ratio is based on the assumption that the biopsy workload is shared and takes into account the increasing use of ultrasound in symptomatic breast diagnosis plus the increasing use of image guided biopsy for both palpable and impalpable abnormalities. This ratio may require revision if the majority of biopsies are performed either with or without image guidance. Due to staffing and imaging equipment constraints many units may need to undertake two clinics per week inviting 20 new referrals to each clinic.

- Four operating lists for breast surgery—six will be required if reconstruction is performed.
- One primary breast cancer follow-up clinic = one session of surgical time per consultant.
- One screening assessment clinic. The session should include a screening meeting (attended by surgeon, radiologist and pathologist from the breast team). Surgical time must be apportioned if the surgeon examines patients at an assessment clinic.
- Multidisciplinary management of patients is essential and this may be achieved by multidisciplinary team discussion in parallel or combined clinics = half session per week per consultant.
- Sessional time to explain, with the help of the breast care nurse, the diagnosis of breast cancer and the treatment options = one session per week per consultant. There should be adequate time to explain clinical trials.
- Continuing care = one surgical session per consultant.
- Multidisciplinary breast meeting = half to one session per consultant.

The overall fixed surgical sessional commitment comprises 14 breast sessions made up of 8–9 clinic sessions, four operating sessions and the multidisciplinary meeting. At least two breast specialist surgeons (consultant or associate specialist) will be required per breast unit. In units where the surgeons have a significant general surgical commitment, more staff will be required.

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 (Table 1).[10]

The breast care nurse should be present, particularly at the time of diagnosis and when options for treatment are discussed. A suitable room with adequate privacy should be available for them to carry out their work. Patients with benign conditions must also be given the opportunity to have questions answered and be given information. Breast care nurses should provide care in keeping with the NHS breast screening standards.[10]

Printed information should be freely available to patients. 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 psychological or psychiatric help.

Breast care nurses should keep up to date with their knowledge of breast disease and there must be an agreed programme of continuing education. They should be involved in the education of other nursing staff on breast disease, both in the hospital setting and elsewhere.

Ideally a breast unit should have at least two breast care nurses and it is essential that they attend the multidisciplinary breast meeting.

Support staff

In addition to the medical staff and breast care nurses, other staff members fulfill important roles. Trained reception staff must be present to assist people on arrival at the clinic. Adequate portering staff for specimen transfer should be available.

Due to the intimate nature of the breast clinic,

Table 2 Quality assurance

Quality objective	Outcome measure
A properly trained data manager should be available to collect data on each patient	More than 90% of data entries for patient episodes should be entered onto the database within 2 weeks of the episode occurring
The national cancer dataset for breast cancer should be available for external quality assurance	The lead clinician of the breast unit must be responsible for production of the above data. It is the responsibility of hospital management to ensure that trained data managers and resources are available. Data managers should be provided as disease-specific core staff, who are part of the breast care team

each doctor in the team should have an accompanying clinic nurse. The nurse should provide a role as a chaperone in addition to their normal duties. Staff training in the skills of good communication will enhance the patient's experience.

Secretarial support

It is essential that the breast team have adequate clerical support to maintain good communication with patients, GPs and other members of the breast team. It is the responsibility of hospital management to provide adequate resource. An example of adequate provision is that which permits all clinic letters to be sent to general practitioners within 1 week of the clinic and all new diagnoses of breast cancer to be communicated to the GP within 24 h. There should be a minimum of one WTE medical secretary per one WTE breast clinician.

Data management

The provision of complete, accurate and timely data requires a properly trained data manager, who is part of the breast team. The breast unit requires adequate resource for information technology and data processing in order to collect patient data prospectively. Annual returns for screen detected and symptomatic cancer data should be available. The resource requirement for data management is often significantly under-estimated.

Standards and audit

Breast units should provide data on the number of patients treated, the treatment received and long-term outcome measures. In order to facilitate uniformity of data, units should collect the national breast cancer dataset. This will include data on local, regional and distant recurrence and long-term morbidity of the primary treatment such as lymphoedema and distant metastases. 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. It is the responsibility of the hospital management to provide adequate resources for this task.

The national breast cancer minimum dataset was revised in 2003. The dataset and revisions are available on the NHS information authority website at: www.nhsia.nhs.uk.

Recommendation
Ongoing audit is essential and should ensure that performance standards are met by all members of the team (Table 2).

The breast clinic

The breast diagnostic process should be carried out in a designated breast clinic, which should provide an environment that allows efficient multidisciplinary clinical practice whilst providing privacy for individual patients.

Each patient should see a trained breast specialist on at least one occasion. Higher surgical trainees (HSTs) may give opinions, providing they have been trained and the supervising consultant has found them to be competent.

Diagnosis should be based on triple assessment, when an initial clinical assessment may be followed by appropriate imaging, fine needle aspiration and/or core biopsy. Not every patient will require each aspect of triple assessment. Triple assessment has a low, but definite false negative rate, which is higher in younger patients.[11]

The inclusion of information leaflets concerning the diagnostic process and investigations with the outpatient appointment letter is recommended. A patient's permission should always be sought before any invasive procedure is performed. Surgeons should provide a clear concise summary of the clinical findings (preferably with scored clinical

degree of suspicion P1–P5) on radiological request forms.

'One stop' clinics

It has been suggested that in ideal circumstances, patients with benign breast disease should receive all required tests and be informed of the results in a single visit to the clinic. This is the concept of the 'one stop' clinic, which was popularised in the 1990s.

However, breast assessment techniques have progressed. The mainstay of the pathology arm of triple assessment has been fine needle aspiration cytology (FNAC), but increasingly core biopsy is used, particularly in patients with a suspected cancer. This can provide information on the presence or absence of invasive tumour, allow provisional assessment of tumour type and grade and enable tumour marker analysis. Interpretation of a core biopsy cannot be performed within the time constraints of a single clinic. The days between clinic visits can allow formal assessment and discussion of suspected cancer diagnoses in the multidisciplinary meeting, prior to a second clinic visit where the patient is informed of the diagnosis and the appropriate treatment options. To inform a patient of a benign diagnosis after full investigation at a first clinic visit is beneficial but it is less certain whether a similar benefit is obtained in patients with breast cancer.

The clinic environment—facilities and structure

Facilities

Adequate consulting and examination rooms should be available to allow patient privacy, permit efficient working practice and enable discussion with breast care nurses and trainees. There should also be specific accommodation for the breast care and research nurses, who may need to speak to patients separately. A unit with a consultant, registrar, clinical assistant and a breast care nurse should have three consulting rooms, six examination rooms and a separate room for the breast care nurse. The whole team should be accommodated in a single clinic unit and not dispersed across different departments or floors.

Ideally, radiology resources should be close at hand with adequate space for mammography, ultrasound and reporting. If desired there should also be space for accompanying pathology facilities such as a room for a cytology mini-lab, microscope, consultant pathologist and MLSO. If the cytology facilities are not included in the immediate clinic environment, adequate portering facilities should be available to permit rapid transport to the pathology laboratory.

Structure

The breast clinic should be structured to provide a rapid, multidisciplinary assessment of the patient with breast disease. For the convenience of patients, diagnostic tests should be programmed to ensure the minimum number of hospital visits. Due to the time that tests may take, patients should be made aware that a clinic visit may take up to 3 h.

Clinic workload

The normal NHS clinic session lasts three and a half hours. During this time the team should be able to see patients and write notes as well as dictating clinic letters. It is important that record keeping is contemporaneous. Model workloads for surgeons have been published previously.[12]

Adequate time should be available for each consultation. Unpublished estimates of the time taken for new patient consultations, fine needle aspiration and discussion show that this takes approximately, 20 min. Follow-up consultations take approximately, 12–15 min but can be substantially longer if a new malignant diagnosis is explained or postoperative histology is discussed. Therefore, a normal session per consultant equivalent should allow 10 new patient consultations or 14 follow-up consultations or a mix thereof. The patient workload should be adjusted to accommodate teaching commitments so that quality of care is maintained.

Adequate time should be available for each new and follow-up consultation. It is paramount that quality of care is maintained in the face of increasing numbers of patient referrals, waiting time targets and the need to manage distressed patients or discuss complex clinical problems.

The hospital management should ensure that the clinic workload is reasonable given the size of the team. Clinics which consistently run overtime, indicate a lack of resources or poor resource-management.

Multidisciplinary case review and planning

Consultants and other team members within the breast unit must have contractual time for attendance at the multidisciplinary meeting. The multidisciplinary meeting is by definition a fixed clinical commitment. It is essential for

Table 3 Multidisciplinary meetings

Quality objectives	Outcome measures
That the management of patients with breast cancer should be assessed by a multidisciplinary team	A multidisciplinary meeting should take place on a weekly basis to consider the clinical, radiological and pathological results of new patients, those with recurrent disease and those who had recent surgery A record of the meeting, including the attendance, should be kept and the conclusions documented in the patients' notes

trainees within breast surgery and its related disciplines to attend the multidisciplinary meeting. A record of attendance should be kept in trainees' logbooks. The conclusions of patient discussion should be recorded in the case notes (Table 3).

Quality standards of diagnosis

Administrative standards

The purpose of seeing patients without delay is to reassure those with benign conditions and to provide patients with breast cancer with a timely diagnosis, discussion of treatment options and supportive care.

It is the responsibility of hospital management to ensure there are adequate facilities and personnel to meet these standards. In the event of insufficient resource being made available, it is the doctor's duty to bring this to the attention of management (Table 4).[13–15]

Radiography and imaging services

Radiography standards

Radiographers who perform mammograms and are part of the diagnostic team should hold the College of Radiographers Post Graduate Award in Mammographic Practice.[16]

Imaging and physics standards

These are the joint responsibility of the physicist, radiologist and the radiographer.

- Physics services should meet the NHSBSP guidelines.[17]
- There should be a quality control programme to monitor and maintain standards.[18,19]
- Imaging of symptomatic patients should reach the same standards laid down for screening.[17]
- Replacement of radiological equipment for mammography and ultrasound should meet NHSBSP standards.
- Mammography equipment for magnification and localisation procedures must be available.
- Ultrasound equipment suitable for breast examination must be available.

Radiology services

Breast imaging services

Breast imaging must be supervised by a specialist radiologist, who is an integral member of the breast

Table 4 Breast clinic

Quality objectives	Outcome measures
To ensure ease of referral to the breast unit	The breast unit must inform GPs how patients should be referred for rapid assessment. This access should include patients with recurrent or advanced disease
To ensure that referrals are seen rapidly	All patients referred by GPs with suspected breast cancer must be seen within 2 weeks of receipt of the referral. All other patients should be seen as soon as possible
To ensure appropriate assessment in the breast unit	Breast units must establish multidisciplinary 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: breast surgeons, breast clinicians, radiologists and radiographers, cytopathologists and breast care nurses
The breast unit should treat an appropriate number of new breast cancer cases	Each consultant's team should treat a minimum of 30 and a maximum of 150 new breast cancer cases per year
To ensure appropriate communication from the breast unit to the GP	GPs should receive appropriate information from the breast unit within 1 week of a patient's clinic appointment

Table 5 Diagnosis

Quality objectives	Outcome measures
To minimise the number of out-patient visits for diagnostic purposes	If imaging and/or cytology or core biopsy are required they should ideally 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. Trainees should have the approval of the lead consultant before seeing patients unsupervised
To minimise patient anxiety between a surgical decision to operate for diagnostic purposes and the first offered admission date	>90% of patients should be admitted for an operation within 2 weeks of the surgical decision to operate for diagnostic purposes
To make a pre-operative cytological or core biopsy diagnosis in breast cancer patients	>90% of patients subsequently proven to have breast cancer should have a pre-operative FNA (C5) or core biopsy (B5) that is diagnostic of cancer
Tumour marker status should be available for all patients with invasive breast cancer	Oestrogen receptor (ER) status should be available for all patients with invasive cancer. Progesterone receptor (PR) status should be available, where ER negative. Other markers should be available when required by the clinical team. HER2 status should be available in advanced disease
Tumour marker testing should be adequately resourced with quality control	Core funding should be available for tumour marker testing. Quality assurance programmes should be implemented in all laboratories undertaking this work

diagnostic team, working closely with the breast surgeon, pathologist and oncologist.[20,21]

Radiology standards

The radiologist should be involved in decisions on the most appropriate imaging investigations. Radiology reports should include a description of significant abnormalities with a characterisation of the level of suspicion for cancer of these abnormalities (R1–R5). It should also include any necessary recommendations for further imaging or guided biopsy (Table 5).[22]

Pathology services

The breast team must include a named pathologist or pathologists with special expertise in breast pathology and cytology, with designated time for breast work. The pathology services should be organised according to the NHSBSP guidelines.[23,24]

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.[25]
- Results of cytology specimens are categorised as follows: C1, inadequate; C2, benign; C3, atypia probably benign; C4, suspicious of malignancy; C5, malignant.
- Results of core biopsy specimens are categorised as follows: B1, unsatisfactory/normal tissue only; B2, benign; B3, lesions of uncertain malignant potential; B4, suspicion of malignancy; B5a, in situ malignancy; B5b, invasive malignancy; B5c, malignant—in situ/invasive status not assessable.

Histopathology standards

Histopathology procedures and reporting should be as described in the NHS BSP document pathology reporting in breast cancer screening.[26] The recording of data for symptomatic patients should be the same as for screen-detected patients.

In particular:

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 on microscopy should be measured in millimetres (mm) and the extent of intraductal and invasive disease recorded in the report.
- The report should comment on an extensive in situ component and where this extends to more than 1 mm beyond the invasive

component (but not lobular carcinoma in situ) there should be a separate measurement.
- Tumours identified as multicentric or multifocal should be appropriately reported.
- The pathologist must report on the width of the excision margin, both radial and deep, and this should be discussed at the multidisciplinary meeting. An adequate margin may be defined as the margin, which ensures a suitably low local recurrence rate in the conserved breast. NICE guidelines suggest that a radial margin of less than 2 mm may be inadequate.[6] There are, however, few data to support this statement. The randomised trials of breast conservation surgery did not specify minimum margin distance and there have been no trials comparing minimum resection margins.
- The surgeon should orientate and mark the specimen prior to delivery to the pathologist. The breast unit must have a clear protocol for the handling of pathological specimens. If a specimen radiograph is performed, this should be available to the reporting pathologist.
- Subtyping of invasive and in situ cancers must use standard nomenclature recommended by the NHS BSP pathology guidelines.[26]
- Histological grading of cancers must be reported using the method described by the pathology guidelines.
- All lymph nodes removed must be examined. The total number of nodes and the number involved by metastases must be stated.
- The presence or absence of lympho-vascular invasion must be stated.
- Progesterone receptor (PR) status should be determined in ER (oestrogen receptor) negative patients with primary or recurrent invasive breast cancer.
- Tumour receptor status for other markers should be determined where it is required by local treatment protocols.
- A formal report for diagnostic pathology should be available within five working days.
- Frozen section with immediate pathological reporting at surgical biopsy should not be done other than in exceptional circumstances. Each occasion should be subject to audit at a MDT meeting.

The referral process

Primary care services

The process of referral from primary care should be simple and clearly identified to permit urgent referral to agreed national guidelines.[27,28]

Access for mammography and breast ultrasound

Mammography is not appropriate as the sole diagnostic test for symptomatic breast disease. The diagnosis of a breast lesion is based on three complementary aspects—clinical examination, imaging and cytology or core biopsy, known as triple assessment. The overall sensitivity of mammography on its own is about 80–85% but is considerably less in young patients.[29]

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 but routine mammography is not recommended for women under the age of 35 where ultrasound is the first imaging method of choice for those with the complaint of a lump.

Screening for women under the age of 50

The results from programmes, which offer screening by mammography to women aged less than 50 years, who are apparently of normal risk, demonstrate smaller benefits than those obtained by screening older women.[30]

There is, at present, no evidence that women on hormone replacement therapy require more frequent mammography than is received through the national breast screening programme.

Family history of breast cancer

Many women with affected relatives present with concern about the risk of future breast cancer but only a minority of breast cancer cases (circa 5%) have a familial element. Breast units should follow agreed written guidelines preferably those of the cancer network, which would include risk assessment, counselling and appropriate surveillance protocols. The identification of individual genetic abnormalities is frequently not possible or appropriate. There is some evidence that when a breast cancer gene mutation is identified risk reduction by bilateral mastectomy or chemoprevention reduces the incidence of breast cancer.

The recommendations from NICE and the association of breast surgery at BASO on family history related breast cancer are awaited in 2004.

Table 6 Management protocol

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

Patient waiting times

Patients, whom the GP suspects of having breast cancer, should be seen within 2 weeks of referral. Breast units should inform general practitioners how they may rapidly access breast clinics.

The association of breast surgery at BASO recommends that all patients are seen as soon as possible to relieve anxiety and because a small proportion of breast cancers are detected in patients with a seemingly benign presentation. The published results of the effect of delays in diagnosis are conflicting,[31,32] but delays of more than 6 months may lead to impaired survival[31] (Level 2 evidence).

Surgical, radiological and pathological findings should usually be discussed at multidisciplinary team meetings before diagnostic results are confirmed to patients.

Communication with the patient

- 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 multidisciplinary breast team and the breast care nurse would 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.

Treatment

Treatment planning

Each breast unit will have written protocols on the treatment of breast cancer, which were formulated and agreed by the breast multi-disciplinary team. The treatment of patients should usually follow these protocols, although it is accepted that there may be reasonable exceptions. The reasons for not following guidelines should be documented.

Following diagnosis, 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 be agreed at a multidisciplinary 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 (Table 6).

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.[33] Planning should enable reconstructive surgery for those women who wish to consider it.

Surgery

Surgical treatment of patients with breast disease must be carried out by surgeons with a special interest and training in breast disease[7–9] (Level 3 evidence). Breast surgeons should work in breast teams, which have the necessary expertise and facilities for a multidisciplinary approach.

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. Reconstruction procedures will require logistical planning but should not lead to significant delay. All diagnostic and therapeutic operations are urgent. An operation for diagnostic purposes should be within 2 weeks of the decision to operate. The maximum wait for therapeutic surgery should be 1 month from the date of diagnosis, except where treatment is planned to be delayed. The NHS cancer plan[5] states that patients should have a maximum wait of 1 month from diagnosis to treatment. In 2002, this standard was extended to a maximum 2 months wait from urgent GP referral to treatment.

Table 7 Surgery

Quality objectives	Outcome measures
To minimise surgical morbidity for impalpable lesions	>90% of diagnostic biopsies of 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 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
To minimise patient anxiety between a decision that a therapeutic operation is required for cancer and the date for operation	Patients should be admitted for the first therapeutic operation within 1 month of diagnosis

To achieve these targets resources must be available, in particular staffing levels must be appropriate. The date of diagnosis is taken as the date on which the first definitive diagnostic procedure (FNAC (C5) or core biopsy (B5)) was performed (Table 7).

Biopsy weight

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 breast cancer screening. This target weight is arbitrary but data from the 1999/2000 audit of screen detected breast cancer confirms that the median weight was circa 20 g.

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 important.

The major randomised trials of breast conservation and radiotherapy vs mastectomy for invasive cancer report local recurrence rates for breast conservation ranging between 3% at 6 years and 17% at 10 years and for mastectomy ranging between 2% at 10 years and 9% at 8 years.[34–37] These trials show that the risk of local recurrence after breast conservation and radiotherapy for invasive breast cancer is 1.5—2 times greater than that following mastectomy (Level 1 evidence). It is suggested that units should achieve local recurrence rates of less

Table 8 Local recurrence

Quality objectives	Outcome measures
Following the treatment of a primary tumour, patients should have ready 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 the early and accurate diagnosis of local recurrence	The surgeon must ensure that adequate follow-up is provided as defined by the unit protocol
To ensure the rapid diagnosis and appropriate management 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 breast conservation for DCIS	Patients with DCIS treated by breast conservation should develop local recurrence at 5 years in less than 20% of cases with a target of 10%
To minimise the development of local recurrence after breast conservation for invasive cancer	<10% of patients should develop local recurrence in a conserved breast after treatment of invasive carcinoma within 5 years, with a target of 5%
To minimise the development of local recurrence after mastectomy for invasive cancer	<5% of patients with primary operable breast cancer should develop local recurrence within 5 years following mastectomy
To minimise the incidence of axillary recurrence	Axillary recurrence should be <5% at 5 years, with a target of 3%

than 10% with a target of 5% after 5 years follow-up. Fewer than 5% of patients, who have had mastectomy, should have chest wall recurrence within 5 years (Table 8).

Axillary node status

The presence of axillary node metastases is the strongest prognostic determinant of 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 and does not include supraclavicular recurrence.

Axillary clearance and level II dissection are effective in controlling regional disease with reported recurrence rates of 3–5% at 5 years.[38–41] It is suggested that axillary node recurrence should be less than 5% at 5 years with a target of 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 axillary clearance[38,42] (Level 2 evidence).

Surgical staging of the axillary lymph nodes should be performed according to local protocols and may include sampling (minimum of four nodes), limited dissection or full level 3 clearance. Sentinel node biopsy (SNB)[43] has been adopted in many countries on the basis of studies showing high rates of sentinel node detection and low rates of false negative node staging.[44,45] Two randomised trials of this technique have recently reported: the ALMANAC randomised trial[46] and the NSABP B-32 trial[47] from the USA. Similar trials elsewhere are ongoing (e.g. SNAC trial in Australasia). The two reported trials show sentinel node identification rates of 97–98% (significantly higher than earlier reports). False negative rates of $<$5–9.7% were reported. These trials suggest that SNB is an accurate diagnostic tool in patients with clinically node negative breast cancer and show considerable improvements in quality of life and morbidity when compared to standard axillary surgery. However, a significant learning curve of 30–40 cases has been demonstrated in both the UK and American trials. In the UK, SNB training using the double identification technique with blue dye and radioisotope is now being arranged for all units under a collaborative arrangement between the association of breast surgery, the Royal Colleges of Surgeons and the Department of Health.

When the sentinel node shows micrometastases (tumour deposit $<$2 mm diameter), further axillary and systemic treatment remains a matter of some debate: some suggest that survival of patients with micrometastases appears similar to node negative women,[48–51] whilst others suggest that their survival is worse.[52–55] Recently, a report[56] has shown significant nodal involvement in patients with a sentinel node showing micrometastases.

Where the sentinel node is truly positive, further axillary treatment (axillary dissection or radiotherapy) as well as appropriate systemic adjuvant treatment is currently recommended. However, the management of patients with positive sentinel nodes is currently under investigation: the EORTC AMAROS trial compares axillary dissection against axillary radiotherapy. The ACOS-OG Z0011 trial compares axillary dissection against observation. These studies will not report for some years.

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. Tumour multifocality is not uncommon and can lead to high local failure rates.[57] 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. Observational studies suggest that high local recurrence rates occur after conservation surgery for diffuse in situ carcinoma. The grade of the tumour[58] and the width of the resection margin[59] are important factors in the management of DCIS.

Two published randomised trials of local excision alone vs excision and radiotherapy have demonstrated a significant reduction in the risk of ipsilateral invasive and non-invasive recurrence in the radiotherapy group at 5 years[60,61] (Level 1 evidence). These data suggest that local recurrence after local excision of DCIS and radiotherapy is approximately 10% at 5 years (Level 1 evidence). The rate of local recurrence after excision alone is approximately, 20% at 5 years in these trials.

Lymph node staging is not normally required in DCIS. However, in cases where DCIS is high grade, appears extensive or presents as a mammographic or palpable mass lesion, invasive cancer may

Table 9 Surgery 2

Quality objectives	Outcome measures
To ensure completeness of excision in breast conservation	Patients with involved circumferential radial margins should normally be recommended to have further surgical excision as defined by local protocol. An adequate surgical margin may be defined as that which results in adequate local control
To minimise the number of therapeutic operations in women undergoing conservation surgery	The number of operations should be recorded and >95% of patients having conservation surgery should have three or fewer therapeutic operations
To ensure that all necessary data are obtained to decide on adjuvant radiotherapy or systemic therapy	Histological node status should be obtained in >90% of invasive tumours in patients having a planned curative operation. Where node sampling has been undertaken a minimum of four lymph nodes should have been obtained in >95% of cases. Clarification on the role of sentinel node biopsy is awaited
To ensure the appropriate treatment of ductal carcinoma in situ (DCIS) in the absence of invasive breast cancer	A mastectomy should be considered if DCIS is 4 cm in diameter or there is extensive micro calcification. Breast irradiation should be considered after breast conservation. Patients undergoing mastectomy for DCIS should be considered for a four node sample. Patients with DCIS alone should not undergo an axillary clearance or axillary radiotherapy

coexist and consideration may be given to axillary staging [but not axillary clearance].

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 cancer[62] (Level 3 evidence). These investigations should not normally be carried out unless the patient is symptomatic or is recommended for neo-adjuvant therapy.[63,64] 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 (Table 9).

Surgery for lobular carcinoma in situ

Lobular carcinoma in situ (LCIS) is often an incidental finding and is usually occult. LCIS is not a local malignant precursor lesion, but it does confer an increased future risk, approximately seven-fold, of invasive breast cancer in both breasts[65–68] (Level 3 evidence). The risk of developing breast cancer is approximately 1% per year. The limited data available on LCIS suggests that a policy of close surveillance may be appropriate (Level 3 evidence) and that clear resection margins are not required for surgery for LCIS alone.

Breast reconstruction

All patients, in whom mastectomy is a treatment option, should have the opportunity to receive advice on breast reconstructive surgery. 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.

Where units offer breast reconstruction, adequate facilities and extra theatre time should be available. Additional clinic time will be required to counsel patients prior to surgery. Facilities should be available for revisional surgery.

Peri- and 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 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 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

Table 10 Radiotherapy

Quality objectives	Outcome measures
To ensure that the appropriateness of radiotherapy is considered in all patients with primary or recurrent breast cancer	The management of all patients with primary or recurrent breast cancer must be considered at a multidisciplinary meeting
To minimise the development of local recurrence after conservation surgery for invasive or in situ carcinoma	Post-operative radiotherapy to the conserved breast should be considered in every case
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 adjuvant radiotherapy to the chest wall
To avoid inappropriate adjuvant axillary radiotherapy	Adjuvant axillary radiotherapy is inappropriate in patients in whom an adequate number of lymph nodes (four or more) are negative

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.

Radiotherapy, endocrine therapy and chemotherapy

- Radiotherapy and chemotherapy should be carried out by clinical or medical oncologists with a special interest in breast cancer and they should be active members of the breast care team.
- Where treatment requires radiotherapy, chemotherapy and hormone therapy, phasing of the treatments should be decided on clinical grounds and the planned intervals should as far as possible be adhered to.

Location of treatment

Treatment should be provided at the breast unit whenever practicable. Radiotherapy is provided at a Cancer Centre but the patient should usually be cared for at the centre by the clinical oncologists from their 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 and administration of cytotoxic drugs.

Radiotherapy

Breast or chest wall 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[34–36] (Level 1 evidence), unless radiotherapy is contra-indicated or the patient is entered into a clinical trial. Patients treated by mastectomy may also be considered for adjuvant chest wall radiotherapy. There is evidence of reduced local recurrence with post-operative radiotherapy in such patients and of improved survival in patients with more severe disease.[69,70]

It is recommended that adjuvant radiotherapy should commence within 6 weeks of surgical resection unless otherwise indicated for clinical reasons.

Axillary radiotherapy

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 multidisciplinary review suggests that there is a particularly high risk of regional relapse. The potential benefit of dual treatment should be balanced against an increased risk of lymphoedema.

Most patients with histologically involved axillary nodes following node sampling should have radiotherapy unless a subsequent axillary clearance is carried out. The requirement for radiotherapy to supraclavicular nodal regions should be determined at the MDT meeting and follow agreed protocols.

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

Patients who have been treated by mastectomy for DCIS do not normally require adjuvant radiotherapy. Adjuvant breast radiotherapy significantly reduces the risk of local recurrence after breast conservation[60,61] (Level 1 evidence) although there are as yet no data on survival. Local protocols should be agreed. Axillary radiotherapy should not be given to patients, who have been diagnosed with DCIS alone.

Recommendation. Patients having breast

conservation surgery for DCIS should be offered adjuvant breast radiotherapy with the possible exception of those with a wide tumour-free clearance and low grade DCIS or as part of a clinical trial (Table 10).

Radiotherapy techniques

The clinical oncologist who is a member of the breast team should be responsible for breast cancer patients from that unit and should direct radiotherapy administration.

Therapeutic radiographers should be appropriately trained, and staffing should be as recommended by the College of Radiographers for the safe use of mega voltage machines.[71]

Endocrine therapy

The overall benefits in cancers responsive to endocrine manipulation are comparable to gains from cytotoxic therapy in patients with ER positive tumours.

Hormone manipulation (e.g. with tamoxifen) is beneficial in patients with ER positive tumours[72,73] (Level 1 evidence).

Current options for endocrine treatment include tamoxifen, aromatase inhibitors, 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 tamoxifen (Level 1 evidence). Endocrine treatment should not normally commence until the oestrogen (and progesterone) receptor status has been determined.

Several recent trials have reported comparing aromatase inhibitors (AI s) against standard tamoxifen therapy for 5 years in the management of postmenopausal ER positive breast cancer. The ATAC study compared 5 years anastrozole against tamoxifen or a combination of anastrozole and tamoxifen. This study showed an improved disease free survival for anastrozole when compared to tamoxifen control or the combination arm at a median follow-up of 47 months.[74] The 5 year data has been recently presented and has confirmed that disease free survival was significantly better and distant recurrence rates were significantly lower in patients on anastrozole compared to patients on tamoxifen. However, overall survival benefit has not yet been demonstrated.[75] The MA-17 study compared the addition of a further 5 years letrozole against placebo after completion of standard tamoxifen therapy for 5 years. Again, women treated with additional letrozole showed an improved disease free survival at a median follow-up of 29 months.[76] The IES-031 study was a randomised crossover study comparing exemestane against continuing tamoxifen after an initial period of 2–3 years of tamoxifen. The study medication was taken until completion of 5 years total adjuvant therapy. This study also demonstrated improved disease free survival in patients switched to exemestane compared with the tamoxifen only group at a median follow-up of 31 months.[77]

These three trials will be followed by further data from ongoing trials (TEAM, BIG-FEMTA) which will add further to the evidence base for hormonal therapy in breast cancer. The data so far suggest improved disease free survival for AI s compared to standard tamoxifen: data for improved overall survival have not yet been published as the trials are not mature enough to demonstrate a significant difference although data has been presented which suggests a significant overall survival benefit for node positive patients taking letrozole in the MA-17 study. At the time of publication, anastrozole has been granted an adjuvant license and letrozole a post-adjuvant license for treatment in early breast cancer by the MRHA. Approval for the use of exemestane in the adjuvant setting is being considered.

In all three trials, AI s showed a lower incidence of thrombo-embolic and endometrial side-effects when compared to standard tamoxifen. However, musculo-skeletal side-effects and reduced bone density were more common in women treated with AI s. No significant increase in osteoporotic fractures was seen in the trials, although longer follow-up may provide further information.

Neoadjuvant endocrine treatment may be appropriate in some instances.

Chemotherapy

Adjuvant chemotherapy prolongs disease-free and overall survival in patients with early breast cancer[78] especially in premenopausal women with ER negative tumours (Level 1 evidence).[72] Where adjuvant chemotherapy is required, the time interval between the decision to give chemotherapy and the start of treatment should not normally exceed 3 weeks. Neoadjuvant chemotherapy may downstage some tumours prior to surgery and may also provide an early indication of lack of response to a specific chemotherapy regime. Taxanes may be used as adjuvant therapy in clinical trials.

Delivery
Cytotoxic chemotherapy should be carried out under the supervision of an oncologist who is a member of the breast care team. There should be adequate pharmacy support. There must also be adequate facilities and medical cover for the management of the complications, which may arise. Patients, staff and GPs must be given full details of how to access this cover.

Management of recurrent disease

Clinical follow-up

Although early diagnosis and adjuvant therapy have improved the outlook for many patients with breast cancer, a significant proportion of all patients will eventually present with 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).[64] 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[63,79–83] (Level 2 evidence).

A recent report by the National Institute for Clinical Excellence (NICE) recommends that routine hospital follow-up is discontinued after 3 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.[6]

The association of breast surgery at BASO has noted the above report and made the following recommendations:

- Patients on continuing active treatment may be followed up until such treatment has been completed.
- 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.
- 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.
- The ideal frequency for mammographic follow-up is not established and current practice is variable.[84] Current UK guidelines from the Royal College of Radiologists[21,85] 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 to be examined and this requirement will need to be resourced.

Follow-up of breast cancer patients known or found to carry BRCA1 or BRCA2 (or other) high risk genetic predisposition to breast cancer

Follow-up
For women at high genetic risk who choose not to have risk reducing bilateral mastectomy, ongoing annual mammography aimed at early tumour detection should be offered in accordance with the guidelines published in 2004 by the National Institute of clinical excellence for high risk women without prior breast cancer [www.nice.org.uk]. Furthermore, an assessment of the risk of ovarian

cancer is important. For BRCA1 or BRCA2 gene carriers or women with breast cancer and other family members with breast and ovarian cancer, the future risk of ovarian cancer may be substantial. Consideration of the role of bilateral oophorectomy is important in each individual circumstance and if implemented must at least include the fallopian tubes even if the uterus is left in situ. There are early indicators from published data that both bilateral oophorectomy and tamoxifen reduce the risk of both breast cancer recurrence and the development of new primary breast cancer in gene carriers.[86,87]

Treatment

In most published data, bilateral risk reducing mastectomy for women at high risk of breast cancer may be chosen by up to 50% of those women shown to carry a BRCA1 or BRCA2 gene mutation.[88,89] A significant proportion of women currently diagnosed with breast cancer will not have had the opportunity to have a genetic diagnosis made prior to their own diagnosis and this may be made after their breast cancer is diagnosed and treated.

Compared to breast cancers in the general population, BRCA1 tumours tend to be more often grade 2 or 3 and ER, PR and HER2 negative, whereas BRCA2 tumours are often high grade but more likely to be ER positive.[90] Current evidence regarding BRCA1 or BRCA2 as independent prognostic factors is limited by methodological problems and small numbers.[91,92]

Some but not all women choose mastectomy at diagnosis of breast cancer either on the basis of family history and experience, or after having a positive genetic test. Current evidence indicates that conservative surgery and adjuvant radiotherapy does not lead to an increase in ipsilateral recurrence of disease in high genetic risk patients in the short term (5–10 years) but in the longer term there may be a greater number of new ipsilateral primaries.[93]

Some women request contralateral risk reducing mastectomy if they consider they have a high genetic risk. This seems to be particularly so if this option is suggested by their surgeon.[94] Since, contralateral mastectomy is essentially protecting against future risk rather than the risk of recurrence of the presenting tumour and complications such as infection may delay adjuvant therapies, relative risks and benefits in the short and the long term require careful discussion with each patient. Preparation should be similar to that offered women prior to risk reducing bilateral mastectomy without cancer and should include an opportunity to examine different surgical options and to review with a psychologist or psychiatrist (with their partner if relevant) their perception of risks and benefits and the potential psychological impact of surgery. Women seem to be more satisfied with the outcome of bilateral mastectomy if they have made this choice for themselves.[95] Partners are often poorly prepared.

Adjuvant therapy

The function of the BRCA1 and BRCA2 genes in repairing double stranded chromosome breaks may have implications in terms of the differential effect of standard adjuvant therapies but much more research is required to clarify this. The use of adjuvant tamoxifen is infrequent in BRCA1 carriers because of the predominance of ER negative tumours in these patients.[96] However, there is preliminary evidence of long term benefit in this group in reducing new primary tumour recurrence.[87] Adjuvant chemotherapy may be more effective in BRCA1 associated tumours even in early stage disease than in the general population but data are limited.[97]

Surgical treatment of recurrent and locally advanced breast cancer

A multidisciplinary approach is needed in the management of patients with recurrent and locally advanced breast cancer.

Local recurrence within the conservatively treated breast

- Isolated local relapse in the conserved breast is often managed by mastectomy.
- Further attempts at breast conservation may be feasible and provide a similar outcome.[98]
- Patients with local relapse should have staging investigations to exclude widespread recurrence.
- Patients with local recurrence as part of systemic relapse should be managed by the multidisciplinary team.

Local recurrence after mastectomy

The incidence of isolated local recurrence in mastectomy flaps is reduced by the use of postoperative radiotherapy. Management depends on the extent of local disease in the mastectomy scar and whether distant metastases are present. Local recurrence presenting as a single spot lesion within the flap may be treated by simple excision with or without radiotherapy. More extensive recurrence with multispot lesions or field change reflects the aggressive biological nature of the breast cancer and may require systemic treatment. The

Table 11 Training and continuing professional development

Quality objectives	Outcome measures
To provide core training in breast disease for all future consultant surgeons	Each higher general surgical trainee should be exposed to breast surgical practice and attain competence in core operations
To ensure good continuing professional development (CPD) for breast specialists	Each breast specialist should attend a minimum of 10 h external CPD per year. Study leave funding must be adequate

management of local recurrence should be agreed by the multidisciplinary team.

Regional recurrence

Regional recurrence may reflect primary treatment failure or the natural aggression of the disease. Uncontrolled axillary recurrence is rare but can be devastating.

Isolated regional relapse may be managed by appropriate salvage axillary clearance or radiotherapy. Patients with metastatic disease and regional relapse will require systemic treatment. The management of regional recurrence should be agreed by the multidisciplinary team. Axillary recurrence rates should be less than 5% at 5 years with a target of 3%.

Locally advanced primary breast cancer

The management of locally advanced primary breast cancer should be multidisciplinary and will require a core biopsy and staging investigations. In medically unfit patients with receptor positive tumours, hormone therapy may be the most appropriate initial treatment.

The management of metastatic disease

Following the symptomatic presentation of distant metastases, average life expectancy is approximately 2 years, with virtually all patients 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 treatment with endocrine therapy and cytotoxics may also give some prolongation of life. Treatment will depend on the site of metastases and a judgement of the likely benefit vs toxicity and the preference of the patient. Palliative measures for bone metastases may include the use of radiotherapy, bisphosphonates and bone stabilisation by orthopaedic surgery. Guidelines in this area were published by the Breast Specialty Group of BASO in 1999.[99]

A patient with recurrent breast cancer should remain under the care of the breast unit in consultation with the cancer unit through multidisciplinary team meetings.

Palliative care

A patient with metastatic breast cancer requires considerable supportive care, which may include relief of symptoms of nausea and pain. The patient's psychological, social and spiritual well-being must also be acknowledged. The expertise of the palliative care team in the hospital and the community should be sought at an early stage.

Monoclonal antibody treatment

The use of trastuzumab should be considered in advanced breast cancer where human epidermal growth factor receptor 2 (HER2) is over-expressed.

Education and training

Continuing education and training

Personnel in breast units must be given sufficient encouragement and time to update their knowledge and skills. The association of breast surgery at BASO arranges regular postgraduate conferences and training courses in conjunction with the Royal Colleges. It is expected that all breast specialists should attend external meetings and visit other units as part of their continuing professional development (CPD). It is expected that every breast specialist should accrue a minimum of 10 h external study per year.

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 (JCHST).[85] A minority of trainees in general surgery will require advanced subspecialty training. If trainees are to progress to an interest in the subspecialty they 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. It is important that trainees are given graded

Table 12 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. Patients should have ready access to information on and entry into suitable trials. Clinical trials facilitators should be permanent members of staff

responsibility, commensurate with their experience and skill and they are given the opportunity for research in breast disease.[100,101] Trainees should not make unsupervised clinical decisions until the lead consultant in the specialty is satisfied that they are sufficiently experienced and are aware of local protocols.

Recommendation
Trainees wishing to become a consultant with a special interest in breast surgery should spend a minimum of 18 months breast orientated training in the final 3 years of their training (Table 11).

Research

Breast units are encouraged to support clinical research and are expected to participate in multicentre studies aimed at improving treatments for breast cancer. They should provide a record of any involvement. There is some evidence that patients treated in clinical trials have improved outcomes (Table 12).[102]

Trained personnel, such as research nurses, are essential and should be specifically employed to coordinate and explain clinical trials in breast disease. They should be employed by the Breast unit as tenured members of staff and not be funded primarily through temporary arrangements such as charitable funding or pharmaceutical donations.

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 January 2008.

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