
The Breast Surgeons Group of the British Association of Surgical Oncology

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

Endorsed by the Senate of Royal Surgical Colleges

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Background

There is a wide gulf between best and worst practice in the diagnosis and management of breast disease.

A woman who finds a breast lump may be able to be seen in a specialist Breast Clinic on the day after she consults her GP, receive all the diagnostic tests necessary and be assured that she is not suffering from breast cancer, in one visit. On the other hand, she may be referred to a non-specialist general surgical clinic, have to wait even months for an appointment, be referred for a mammogram weeks later, be seen several times by junior staff at the surgical clinic and finally receive an inappropriate operation for removal of her lump.

A woman with diagnosed breast cancer may be offered a choice of primary treatment by a Breast Surgeon, who has validated criteria for knowing that treatment with breast conservation is appropriate in that patient, and be able to discuss this with a breast care nurse who regularly works with that surgeon and knows the approach taken. On the other hand, she may be poorly advised, receive breast conservation but because adverse features are present, suffer an extensive local recurrence; she may receive no explanation or choice of procedure.

After the operation she may be correctly advised on whether she needs adjuvant radiotherapy and systemic therapy, advice based on measured prognostic factors. Or these factors may not have been measured at all, e.g. lymph node biopsy, and she may receive unnecessary treatments or be deprived of appropriate prophylaxis.

These are not exaggerated pictures and surgeons will recognize both ends of the spectrum.

A good Breast Unit will audit its performance, in the long, as well as the short term. The surgical 'occasionalist' (from the breast cancer point of view) does not have enough cases for meaningful audit, which is even less helpful if a variety

of non-specialist radiologists and pathologists are reporting breast cases in that hospital.

At present there is no health services research that has identified best practice in breast disease; but there are clear problems, as identified above, and these can be remedied by changes in organization. Furthermore, the necessary changes can be made now. Several reports²⁻⁴ demanding change have recently appeared: the Cancer Relief Macmillan Fund has identified deficiencies in practice and calls for them to be remedied; the multidisciplinary British Breast Group has pointed to the advantages of specialization in breast disease; the Advisory Committee on Cancer Services to the Chief Medical Officer recommends the establishment of Breast Cancer Units, staffed by specialists in that condition.¹⁻⁴

The GP sees only around 20 breast cancers in his or her practice lifetime and is therefore likely to refer most breast cancer problems to a specialist; women with breast symptoms account for around one in five of all patients referred for surgical opinion. Not all need breast imaging from the radiologist; those with cancer are initially managed by the surgeon and only some need treatment from the clinical oncologist. It is therefore the surgeon who has the lead role in breast disease. To maintain this role surgeons need to acquire specialist skills and to become members of breast teams in Breast Units and have to be given contractual sessions for breast disease.

When NHS breast screening was introduced the disciplines involved were required to establish specialty groups. The National Surgical Coordination Group for Breast Screening was formed within the British Association of Surgical Oncology (BASO). This group published guidelines, approved by the Royal Colleges, for surgeons in breast screening. The BASO group then saw a double standard applying in breast disease: screen-detected cases received a good service from specialists, backed by Guidelines and overseen

and audited through a National Screening Coordinator. For women presenting symptomatically there is no such structure. It is to address this problem that the Guidelines for Symptomatic Breast Disease Management have been produced.

Each specialist surgical group has its own specialty organization and within the overall structure of surgical organization the subspecialties of general surgery are represented by the Association of Surgeons of Great Britain and Ireland. The Association has the BASO group as its advisers on breast surgery, through the Specialties Board. The BASO Breast Group has widened to try to include all surgeons specializing in breast disease. Any surgeon who has breast disease as their major subspecialty and is a member of BASO, acquires membership to the BASO Breast Group. An expanded Steering Group within this organization, has an elected structure and the breast specialty organizations of other disciplines have representation on this Steering Group. The Guidelines are being processed through the Association of Surgeons and have been approved by the Royal Colleges.

A surgical structure for the care of breast disease is now in place to sit alongside the national initiatives. This document identifies good practice for surgeons in breast disease and the management of breast cancer and gives auditable standards. It also lays down, for provider units, the needs of a Breast Surgeon who is expected to provide a specialist practice, such as expertise from fellow members of the breast team and the provision of high quality breast imaging.

Increasing knowledge of any disease results in new methods of diagnosis and treatment; in their turn these need a greater depth of understanding, hence the growth of specialization. In breast disease specialization is resulting in a greatly improved standard of care for women.

The present Guidelines for Surgeons in the Management of Symptomatic Breast Disease have been produced by the National Coordination Group as a whole, worked-up by a subgroup (Hugh Bishop, Paul Preece, Mike Greenall and Joan Austoker), Hugh Bishop became the Secretary for the Guidelines, and Hugh and I have spent a great deal of time bringing them to publication. Final drafts were approved by the National Coordination Group and before that were debated by 170 breast surgeons at a workshop organized by the National Coordination Group in June 1994. Extra changes have been made following readings by the Cancer

Committee of the Royal College of Surgeons of England, by the Specialties Board of the Association of Surgeons and in response to comments from a small group appointed by the Association of Surgeons to review the Guidelines.

A considerable debt is owed to Julietta Patnick, the National Coordinator for Breast Screening, who has given great encouragement and, most important, obtained funding for the writing of the Guidelines. A generous educational grant from Zeneca Pharmaceuticals has paid for publication and distribution of the Guidelines. I also thank Vivienne Brown, Wendy Bartlam, Judith Dunlop and Veronica Hall for their secretarial work.

Roger Blamey, MD, FRCS

*Chairman of the National
Coordination Group for Breast Surgery*

The emergence of breast surgery as a defined subspecialty of general surgery has led to improving standards in the care of patients with breast disease.

This document compiled by the Breast Surgeons Group of BASO has had a widespread professional input from BASO, the British Breast Group, the National Surgical Coordination Group and with input from the Royal Surgical Colleges.

As immediate past President of the Royal College of Surgeons of Edinburgh, and as a surgeon whose practice has predominantly been in breast disease, I warmly recommend these practical, sensible and very necessary guidelines to the management of symptomatic breast disease.

A Working Party of the Royal College of Surgeons of England that I chaired in the late eighties called for sophisticated specialization in the management of screen-detected cancer. The subsequent document on quality control from the National Group has been valuable and the latest contribution is a logical further step to assure skilled, sensitive and coordinated management of women with breast problems.

The profession and public will be grateful to those who have contributed expertise and time. This truly national team brings all interested parties together in a well-constructed and most necessary document.

Professor P. S. Boulter

The guidelines for surgeons in the management of symptomatic breast disease in the UK

The breast unit

The Advisory Committee to the Chief Medical Officer on Cancer Services⁴ has suggested that care of malignant disease be given through Cancer Centres and Cancer Units. The Cancer Units are visualized to be District General Hospital based and to manage the diagnosis and initial treatment of the common cancers in cancer site-specific units, i.e. one District General Hospital might have a Breast Cancer Unit, another a Colon Cancer Unit, etc. This essentially means that to build Breast Cancer Units needs the establishment of specialist teams to look after breast cancer.

In the same vein a report produced by the British Breast Group³ calls for breast cancer to be managed by surgeons, radiologists, pathologists, clinical and medical oncologists and nurse specialists, each of whom specialize in breast cancer and work as a team. The British Breast Group report suggests that a minimum of 50 new breast cancers per annum should allow recognition as a Breast Cancer Unit: but this figure was given for unusual geographical situations ('Highlands & Islands')—the feeling was towards units with 150 new breast cancers annually; certainly this number maximizes the arrangement of specialists in each discipline having contractual sessions for breast cancer and working in joint clinics.

The Breast Cancer Unit will be based in the District General Hospital. The calculations for expected patient numbers and the time commitment for specialist staff, are shown in Section 16. It is likely that most District General Hospitals will have a Breast Cancer Unit, however, 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 Guidelines for Surgeons are both in the same direction. 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. A woman would not be referred from general surgeon to general oncologist, etc., but would remain permanently under the care of the one team of breast specialists.

A considerable amount of the surgical work of a District General Hospital is breast disease—roughly equating in numbers of patients and operations to the workload for urology, or for gynaecology. Like these specialties there is advantage to having a breast disease directorate or certainly a separately identified breast budget; the budget should include screening and care of advanced disease.

The surgeon has a central role in establishing the Breast Unit, for the cases are usually referred to the surgeon and apart from screening, the first contact is with the surgeon. A great deal of the work of a Breast Unit is outpatient, surgically led and much of the work has been referred to as

'reassuring the worried well'. This considerable diagnostic workload has to be borne in mind when surgeons seek to have a number of sessions identified for breast work.

The Surgeon does not necessarily need to take on the post of director of the breast unit but has the lead role in the design of and responsibility for, diagnosis of all cases, initial treatment of cancers and the follow up of primary cancer (especially if treated with breast conservation).

The specialty of Breast Disease is now established. No longer should a patient be content with referral to any surgeon but should be able to attend a Breast Clinic where there is special expertise. This is increasingly demanded by patients and therefore by purchasers, and provision is already being made in many districts.

Primary care services

In the UK referral to a Surgeon is via a General Practitioner. It is essential that General Practitioners establish links with Breast Units and are able to arrange urgent referral when required. Contacts must include provision for communication to the GP of the diagnosis and proposed treatments (Table 1).

The majority of women who present to the GP with breast symptoms do not have breast cancer. Initial investigation of breast symptoms should be by clinical examination. If there is any doubt in the GP's mind that the breast is other than entirely normal then an opinion from a breast surgeon should be sought. Symptoms requiring such opinions are:

- Lump
- Nipple discharge
- Nipple eczema
- Skin or nipple tether

Aspiration of breast lumps by General Practitioners

- Breast lumps should only be aspirated by GPs when they have acquired experience in the technique and when it is very likely that the lump is a cyst, i.e. when the lump is smooth and when the patient has had a previous cyst aspirated.

Table 1.

Quality objectives	Outcome measures
To ensure ease of referral to the Breast Unit	The Breast Unit must send details to GPs of how patients can be referred for rapid access. This includes established cases already under the care of the breast clinics, e.g. those with advanced disease

- If after cyst aspiration there is a residual mass then referral to the Breast Surgeon is mandatory.
- Cyst fluid should not routinely be sent for cytology.

The advantage of the GP aspirating a cyst is the immediate relief of anxiety and avoidance of an outpatient referral. The disadvantage is that if the lesion proves to be solid rather than cystic, the imaging appearance may be distorted by needling and interpretation of a subsequent fine needle aspirate may be very difficult. Also a lump may be caused by needling (haematoma) leaving the surgeon uncertain, at subsequent referral, as to whether he/she would have thought that a true lump was present in the first instance. The particular skill and training of the breast surgeon lies in deciding whether a true lump is present or not. It is often difficult to differentiate between a true lump and a lumpy area and unless the aspirator is certain that a lump is present then needling is contraindicated.

Access for mammography

- Direct access for GP referral for mammography is not recommended. Open access mammography is unnecessary if access to a breast clinic is adequate.

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 three complementary aspects—clinical, imaging and cytology, 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 cancer may not be visible on a mammogram, particularly in a young woman.

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.

Women on Hormone Replacement Therapy

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

Screening for women under the age of 50

- There is no 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 onto HRT at this age).

Family history of breast cancer

Many women are concerned that they are at an increased risk of breast cancer because they have a relative who developed the disease. Current views are that women with two first-degree relatives who developed breast cancer or one first-degree relative who developed the disease before the age of 50, are at increased risk. Many who seek advice can be reassured that they do not have a significantly

increased risk. Research is being undertaken nationally into the benefits of screening patients with a family history. Genetic marker tests are not yet developed for use as indicators of risk. Where a local family history clinic exists it provides an opportunity for women with a family history of breast cancer to obtain risk assessment and advice on the need for screening.

- Referral to a family history clinic, for women with a family history of breast cancer, provides an opportunity for risk assessment, counselling, possible early detection and the opportunity to take part in prevention studies and other research programmes.

Diagnostic services

The breast diagnostic process should be carried out in a designated Breast Clinic. When a Breast Screening Assessment Unit is close by it would seem logical to combine the two facilities (staff and equipment). Diagnosis should be based on Triple Assessment, which initially is clinical opinion, and may require imaging and cytology or needle histology.

- 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.
- To maintain expertise such a clinic needs to diagnose a minimum of 50 cancers per year. To be cost-effective this figure is 100–150.
- The Breast Clinic should be structured to produce a rapid and multi-disciplinary assessment of the woman with breast disease. For the convenience of patients, diagnostic tests should be programmed to ensure the minimum number of visits.
- The majority of patients with no true abnormality or with a benign lesion, should receive all diagnostic tests at the single visit. Most may then be told that there is no abnormality or that their lesion is likely to be benign, by the end of that appointment.
- Patients who have newly diagnosed breast cancer may be given their diagnosis at the initial visit but usually require a second attendance, at which the Breast Care Nurse should be present with the Surgeon to help the patient come to terms with the diagnosis and make an informed choice about treatment. Patients should be encouraged to

Table 2.

Quality objectives	Outcome measures
To ensure rapid referral	Breast Units must establish multidisciplinary designated 'Breast Clinics', for new patient referral
For women to be seen by breast specialists	The clinic should be served by staff specially trained in breast disease: surgeon, radiologist and radiographers and with specialist pathologist-cytologist back-up

bring a partner or friend with them when the results are being discussed. The needs of patients whose first language is not English may require special attention.

- Patients should not receive abnormal results by telephone or letter.

Attention is drawn to the booklet recently published by the NHSME on patients' perception of services.⁵

Quality standards for diagnosis

Quality Assurance standards for the diagnosis of breast cancer include:

Administrative standards

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

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

Table 3.

Quality objectives	Outcome measures
To ensure that <i>urgent</i> referrals are seen rapidly	>80% of <i>urgent</i> referrals (as deemed urgent by the surgeon), are to be seen within 5 working days of receipt by the Hospital of the referral. If referral letters are sorted by the surgeon to 'urgent' and 'normal' it is a managerial responsibility to ensure that the Surgeon sees the letter shortly after its arrival
To minimize the delay in seeing all new referrals	70% of all other new referrals to be seen within 15 working days

Clinical standards

Table 4.

Quality objectives	Outcome measures
To minimize the number of outpatient visits for <i>diagnostic</i> purposes	If imaging and/or cytology or needle biopsy are required they should be performed at the initial visit <10% of <i>all</i> new breast patients should be required to attend the Hospital on more than two occasions for <i>diagnostic</i> purposes
To ensure that patients attending for diagnostic purposes are seen by a surgeon with special training in breast disease	Patients attending for diagnostic purposes should be seen at least on one occasion by a breast specialist surgeon (consultant surgeon, associate specialist with special training in breast disease) or level 3 trainee in breast surgery. This will be attainable only when numbers of consultant surgeons are increased. At present service demands means that higher surgical trainees are required to see patients in diagnostic clinics. Higher surgical train-

Table 4—continued.

Quality objectives	Outcome measures
To minimize the interval from a surgical decision to operate for diagnostic purposes and the first offered admission date	needs should only give unsupervised opinions in breast diagnostic clinics when judged competent to do so by the supervising consultant. They must <i>also</i> have been on the breast unit for at least 2 months, to ensure that they have adequate knowledge of local diagnostic protocols. >90% should be admitted for an operation within 2 weeks of the surgical decision to operate for <i>diagnostic</i> purposes
To produce an FNA sample that can be incorporated into the Triple Assessment process	>90% of FNA samples from lesions which subsequently prove to be cancer should be adequate as deemed by the breast pathologist

Table 5.

Quality objectives	Outcome measures
To minimize surgical morbidity for impalpable lesions	>90% of diagnostic biopsies which <i>subsequently prove benign</i> , for impalpable lesions, should weigh less than 20 g. The Surgeon should ensure that the weight is recorded in theatre or by the Pathologist
To reduce the number of open surgical diagnostic operations	The Benign-Malignant operation rate (this is the number of open surgical biopsies which prove benign to the total number of breast cancers diagnosed on the Unit) should be no more than 1:1 (operations for nipple discharge and abscesses are excluded)
To minimize the number of pre-operative diagnostic frozen sections	90% of palpable breast cancers should be diagnosed pre-operatively (by cytology or needle histology) <10% of primary operable breast cancer should receive a frozen section
To minimize the interval between diagnostic tests and communication of results	Patients with no abnormality should be given their results at the initial visit (outcome measure: more than 90% of such patients) >90% of patients proving to have breast cancer or an abnormality requiring diagnostic operation, should be told of this within 5 working days of carrying out investigations which lead to this diagnosis Patients judged likely to have benign lesions will have been investigated by cytology or needle histology. >90% of patients undergoing these tests should receive their results within 5 working days

Radiography, imaging and physics standards

- Radiographers taking mammograms should hold the College of Radiographers Certificate of Competence in Mammography.
- 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 Programme⁶ 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 care diagnostic team.

- Physics services should meet the guidelines set out in their publication.⁷
- Units should have in place a quality control programme to monitor and maintain standards.⁸
- In order to achieve image quality of at least the minimum standards laid down for screening, radiology services should optimize the quality obtained in their existing equipment including films, screens, cassettes and processors.⁷
- Mammography X-ray equipment, when due for replacement, should be replaced by equipment meeting NHS BSP standards.

Radiology services

Breast imaging services

Breast imaging should be reported by radiologists experienced in breast imaging (mammography and breast ultrasound). The radiologist is an integral member of the breast diagnostic team who should work closely with the breast care surgeon. The surgeon and radiologist should be able to consult together regularly and preferably the radiologist should work in the diagnostic Breast Clinic.

Radiology standards

- Minimum standards for radiologists involved in the NHS Breast Cancer Screening Programme have been published⁹ and The Royal College of Radiologists Breast Group has produced guidelines for Radiologists involved in symptomatic mammography.¹⁰ Radiologists involved in breast imaging should meet these standards.
- Sophisticated mammography equipment, including magnification and localization capabilities should be available.
- Ultrasound equipment suitable for breast examination should be available.

- Reports of imaging examinations should include detail of the site, size (in mm) and nature of any abnormality, with an opinion as to the most likely diagnosis and any further intervention recommended.
- Multidisciplinary review should take place of results of diagnostic tests.

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 pathologist should be based in the same hospital group as the surgeon and be a member of the Breast Unit team.

Cytology standards

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

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

as in the *Guidelines for Cytology Procedures and Report*.¹¹

- Multidisciplinary review of the cytology results should be undertaken regularly.

Histopathology standards

Histopathology procedures and reporting should follow the NHS BSP document *Pathology Reporting in Breast Cancer Screening*, which is at present being updated.¹² The same data as are provided for breast screening should be provided for symptomatic patients.

In particular the following points are extracted from the guidelines:

Managerial

- Histopathology departments and surgeons must have access to specimen radiography facilities.
 - Multidisciplinary review of histology results should take place regularly and it is recommended that the breast care team meets at least once a week to discuss the post-operative histology.
 - 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 recorded in the report.
- The report should comment on the extent of disease and whether the tumour contains an extensive *in-situ* component. Tumours identified as multicentric should be so reported.
- The report should comment on the involvement of surgical excision margins by tumour and the extent of disease. 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 (see Table 10). The Breast Care Unit must have a clear protocol for the handling of pathological specimens.

- Subtyping of invasive and *in-situ* cancers should use standard nomenclature as recommended by the NHS Breast Screening Programme in the pathology guidelines.
- Histological grading of cancers should be undertaken using the method described by the pathology guidelines. Results should be incorporated into the report.
- Adequate numbers of the lymph nodes identified in material submitted to the pathologist should be examined.
- The presence or absence of vascular invasion should be stated.

Treatment planning

Treatment of the primary tumour must follow written protocols agreed by the Breast Team, e.g. criteria for acceptance for treatment with breast conservation etc.

Following diagnosis, women must be given adequate time, information and support in order to make a fully informed decision of their treatment. This should include discussion with the surgeon, in liaison with the breast care nurse, of suitable treatment options. The offered options and the decisions made should be recorded, particularly when a patient is entering a clinical trial.

Table 6.

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

Close communication must be maintained between surgeons and radiotherapist/oncologist to plan primary treatment and facilitate subsequent adjuvant therapy. A care plan for each woman should be drawn. Considerations in framing this must take account of factors predictive of both survival (lymph node status, Nottingham Prognostic Index)¹³ and of local or regional recurrence, the age and frailty of the patient, social circumstances and patient preferences. Planning should also allow for the availability of re-constructive surgery for those women who wish for it.

Surgery

Surgical treatment of breast disease should be carried out by surgeons with a special interest and training in breast disease. Breast surgeons should work in Breast Units which must provide the necessary expertise and facilities for a multidisciplinary approach to this common malignancy.

In a case in which treatment with breast conservation is unwise and mastectomy is to be, or has been, carried out there should be the opportunity for patients to receive advice on reconstructive breast surgery. This may be available in the Breast Unit; otherwise the Breast Team should have a recognized line of referral to a plastic surgeon with particular expertise in breast reconstruction. There should be adequate

Table 7.

Quality objectives	Outcome measures
Treatment of breast cancer should be carried out by staff with special expertise and training in breast disease	A Breast Cancer Unit must have specialist expertise in breast surgery, breast imaging, breast pathology (including cytology), anti-cancer drugs used for breast cancer, breast radiotherapy and clinical nurse support (breast care nurse)

facilities for: outpatients; inpatients; day patients; and theatre sessions.

Secretarial support

A breast practice generates a large number of events (clinic appointments, operations, etc.). It is important that the breast team is adequately supported in order to communicate effectively.

Multidisciplinary case review and planning

It is crucial that there is a defined time within the working week for the Breast Team to meet to discuss diagnosis and agree treatment plans for individual women.

Table 8.

Quality objectives	Outcome measures
Multidisciplinary discussion of patients undergoing treatment for primary breast cancer	A formal multidisciplinary meeting to consider the pathology of cases recently operated upon and discuss further treatment attended by members of the breast care team involved in primary treatment (particularly Surgeon, Pathologist, Clinical Oncologist and Breast Care Nurse) held weekly

Avoidance of delay

Once a decision has been reached, patients should be offered a date for operation, rather than be placed on a waiting list. Urgent operations are those to be carried out for therapeutic purposes when there is a proven diagnosis of cancer, or where the operation is being carried out to establish the diagnosis (i.e. to confirm or exclude malignancy). These are urgent rather than emergency operations but nevertheless the patient waits with a great deal of anxiety and admission should be as soon as possible. It is good practice for the operation date to be within 2 weeks, and the maximum acceptable wait should be 4 weeks, except where treatment

is planned to be delayed, e.g. to follow primary cytotoxic treatment.

Table 9.

Quality objectives	Outcome measures
To minimize the interval from a surgical decision that a therapeutic operation is required for cancer	90% of patients for therapeutic operation for cancer should be admitted within 3 weeks of informing the patient of the need for surgical treatment

Surgical procedures

Surgeons are reminded that all breast operations should be carried out either by trained breast surgeons or by trainees with sufficient training in breast disease (see Table 4), or by trainees under direct supervision at operation.

Some 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.

Peri-operative systemic investigations

There is good evidence that a peri-operative search for occult metastases (e.g. bone scan, liver ultrasound) does not yield any useful information in a woman with operable primary breast cancer. These investigations should not be carried out at that stage. They are essential for the investigation of symptoms in the follow-up clinic.

Surgery for primary operable breast cancer

Table 10.

Quality objectives	Outcome measures
To ensure completeness of excision in breast conservation	The surgeon must ensure that the gross margins are identified without incision into the specimen and that the specimen is carefully orientated for the pathologist
To minimize 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 no more than two <i>therapeutic</i> operations
To ensure that all necessary data are obtained for making decisions on adjuvant radiotherapy or other systemic therapy	Histological node status should be obtained on all invasive tumours either by sampling or clearance. It is recommended that 'a sample' should contain four lymph nodes that the surgeon has identified and dissected

Peri-operative and follow-up care

Patients should be supported by a clinical nurse specialist (Breast Care Nurse), who is a member of the Breast Team

Table 11.

Quality objectives	Outcome measures
To avoid unnecessary adjuvant therapy	Prophylactic axillary radiotherapy is inappropriate in cases in which adequate numbers of lymph nodes (at least four) have been examined by the pathologist, to conclude that the patient is histologically node-negative
To ensure the appropriate treatment of ductal carcinoma <i>in-situ</i> (DCIS)	A local excision is not appropriate for extensive lesions Axillary clearance or radiotherapy to the chest wall or axilla following mastectomy, are contra-indicated The surgeon is encouraged to know the criteria for entry to the DCIS trial

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. Since support groups may be well-meaning whilst misinformed on occasions, it is desirable that they 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 and care plan and toxicity profile of any proposed systemic treatment. Such communications should certainly be sent at the first post-operative review and at the change of any treatment.

Standards and Audit

Units should be in a position to provide data on the number of patients treated and by what methods. They should be able to report the long-term outcome measures in treating women with breast cancer. These will include data on local and regional recurrence, long-term morbidity of the primary treatment, e.g. lymphoedema, uncontrolled local recurrence, distant metastases and death.

Table 12.

Quality objectives	Outcome measures
Outcome measures are available for inspection by the purchaser	Either the surgeon on the Breast Unit or the clinical director of the Breast Unit, must have overall responsibility for production of the above data by the Unit

The Breast Care Nurse

As part of the Breast Care Team, the Breast Care Nurse should be available for all patients undergoing treatment for breast disease.¹⁴

The Breast Care Nurse should be present, particularly at the time of diagnosis, when any options for treatment are discussed. A suitable room with privacy should be available at this time. As the patient may be emotionally shocked, she probably will not take in everything she is told; the presence of a companion (e.g. husband or friend) helps here. A telephone contact number and/or further appointment may be made to discuss treatment again and answer any questions. Even women with benign conditions may sometimes have questions and need information.

Table 13.

Quality objectives	Outcome measures
To minimize the development of local recurrence in the conserved breast	<10% of patients developing local recurrence within 5 years

The nurse should be available to see patients pre- and post-operatively on the ward, where such matters as arm exercises and minor 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 is given on subsequent visits to outpatients when women may receive their results and further treatment discussed. Patients are offered advice on bras, swimwear and choice of permanent prosthesis, 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 are watched for signs of anxiety and depression and are referred, where appropriate, for specialist psychiatric help.

The nurse should keep herself up to date with knowledge of breast disease; this is helped by taking part in research. 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, working together but with one largely working at the primary stage and one largely for help in advanced disease.

Follow-up

Although early diagnosis and newer multimodality treatments have improved the outlook for many women with breast cancer, approximately 60% will suffer some form of recurrence, and one-half of all patients will eventually present with distant metastases and die from their disease. The chances 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 Index¹³, at the time of initial treatment. Two-thirds of all recurrences occur during the first 5 years after treatment,

Table 14.

Quality objectives	Outcome measures
To ensure early and accurate diagnosis of any local recurrence	The surgeon must ensure that adequate follow-up is provided. There must be involvement of the surgical team in the follow-up of patients treated with breast conservation

the incidence of events decreasing exponentially with time. Following treatment patients are at increased risk of:

Local recurrence within the treated breast, when this has been conserved

- Local recurrence is defined as further breast cancer within the skin or parenchyma of the treated breast (whether considered a recurrence or new primary tumour).
- The unit must have a written protocol to decide which patients have tumours that are suitable for conservation therapy—if a tumour has unsuitable features then mastectomy should be advised.
- The detection of local recurrence following conservation surgery requires the same approach 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 as for the diagnosis of primary breast cancer.
- The optimum frequency of clinical follow-up is not established but we suggest the patient is followed up every 6 months for the first 5 years and annually thereafter.
- Similarly the ideal frequency for mammographic investigation is not established but we suggest annual mammography of the treated breast.
- Facilities should be available to allow these.

Table 15.

Quality objectives	Outcome measures
To minimize the development of local recurrence after mastectomy	<10% of patients with primary operable breast cancer developing local recurrence within 5 years. There should be a written protocol which identifies those patients at high risk of flap recurrence. Prophylactic radiotherapy can then be employed in these women

Local recurrence following mastectomy

The advantages to follow-up by the Breast Team are that local recurrence in mastectomy flaps may on occasion be difficult to recognize (for example, when it presents as an eczematous appearance of the flaps), and is most easily recognized by a surgeon expert in the treatment of breast cancer. Distant recurrence may sometimes be difficult to

recognize (for example hypercalcaemia; endobronchial disease; lymphangitis of the lung; bone pain) all these are most easily recognized by a specialist regularly dealing in breast disease. The General Practitioner, it must be appreciated, will see on average only one new patient with metastatic disease from breast cancer every 3–4 years.

- We suggest that patients should be seen every 6 months after mastectomy for the first 5 years and annually thereafter. 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. Whether regularly followed-up or not, women who have undergone treatment for primary breast cancer should have open access to a follow-up clinic, should they be worried about any sign or symptom.
- If a General Practitioner detects recurrence referral should wherever possible be back to the Breast Unit and not to some different surgeon or oncologist. This implies that there must be a clear mechanism for the General Practitioner to have access to the Breast Unit when problems arise

Table 16.

Quality objectives	Outcome measures
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 access the breast care team (which may be through the Breast Care Nurse)
To ensure that symptoms of recurrent disease lead to a correct diagnosis	Written guidelines on the detection of recurrence (local, regional and distant) must be given to all medical staff engaged on the follow-up clinic

Contralateral primary breast cancer

Previous breast cancer increases the risk of a second primary by four. Women who develop their first cancer below the age of 40 are at much higher risk.

- We suggest that the contralateral breast should be examined by mammography at least every 3 years.
- The use of tamoxifen may decrease the incidence or may simply slow the appearance of a second primary breast cancer.

Treatment of local and regional recurrence and of locally advanced breast cancer

The acquisition of plastic surgical techniques by the breast care surgeon or cooperation with a plastic surgeon may be required in dealing with these conditions.

Local relapse within the conservatively treated breast

Relapse will usually be managed by a mastectomy.

Local recurrence after mastectomy

The incidence of local recurrence in the mastectomy flaps is influenced by the extent of the operation and by the use of radiotherapy. Local recurrence may be a single spot within the flap treated by simple excision. More extensive recurrences reflect the aggressive nature of the breast cancer, e.g. dermal lymphatic invasion. Recurrences of this nature should be dealt with by a combined approach from the Surgeon and Clinical Oncologist, who are members of the Breast Team, who should manage the patient in a Combined Breast Clinic.

Treatment of regional recurrence

Regional recurrence is a reflection of the primary treatment as well as the natural aggressiveness of the disease. The majority of women with breast cancer do not develop symptomatic regional recurrence, therefore it is necessary to identify women at low risk of regional recurrence who will not then be subject to axillary clearance or to prophylactic radiotherapy. Most women with a positive axillary node sample should have radiotherapy unless they have had an axillary clearance.

Table 17.

Quality objectives	Outcome measures
To diminish the incidence of regional recurrence	Regional recurrence needing further surgery or radiotherapy should be <10% at 5 years. Surgeons must obtain adequate information about lymph node status in the axilla (see above Section) and employ appropriate prophylactic treatment when the nodes are invaded

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 oncologist/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 therapies. Local control may usually be gained by a combination of treatments—radical surgery (sometimes including myocutaneous flaps/grafting procedures) and/or radiotherapy and systemic treatments. Achievement of local control of disease and symptomatic relief is of great importance.

The management of metastatic disease

At the symptomatic presentation of distant metastases, average life expectancy is around 2 years, with virtually all 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 likelihood of benefit, the potential toxicities of different treatments and the preferences of the patient. These include systemic anti-cancer therapies and palliative measures, such as radiotherapy for bone metastases, bone stabilization by orthopaedic surgery, pleurodesis, etc.

The conclusion of the British Breast Group *Provision of Breast Services in the UK: the advantages of Specialist Breast Units* is that with the exception of having to receive radiotherapy the proper care of patients with breast cancer should be centred at Unit (district) Level.³ This carries the implication that patients should not be followed up in the Cancer Centres but should simply receive their radiotherapy there and then return to Unit Level for further follow-up clinics or for any other necessary therapies.

Once the patient develops symptoms from distant metastases she should remain under the care of the Breast Unit. Treatments must be to protocols agreed within the Breast Care Team. A specialist surgeon not only treats primary breast cancer but 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 of the non-surgical oncologists within the breast care team. The majority of the treatments and all clinic assessments should take place in the Cancer Unit, rather than the Cancer Centre.

Throughout the time that a patient suffers from metastatic disease, it is essential that she receives optimal supportive care. This will include relief of symptoms (e.g. pain control with analgesics) and attention to the patient's psychological, social and spiritual well being. The involvement of palliative care teams in the hospital and in the community may be sought.

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

Radiotherapy, endocrine therapy and chemotherapy

- Radiotherapy and chemotherapy should be carried out by clinical oncologists and medical oncologists who have opted to specialize in breast cancer. They should have special training and interest in breast cancer, be seen as members of the breast care team and treat the patients from the team. They will have expertise in: the use of radiotherapy in breast cancer; the use of systemic treatments for breast cancer (hormonal or cytotoxic); and the relief of symptoms associated with metastatic breast disease.
- As with surgery there is evidence that outcomes are better if treatment is prescribed by and supervised by a medical or clinical oncologist with an interest in breast cancer.

Place of treatment

Where practicable, treatment should be provided at the Breast Unit. 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 which complies with the requirements for the safe handling of cytotoxic drugs and with adequate trained supervision.

Ongoing care in advanced disease

- To ensure continuity of care by one team and to minimize travel problems. Clinic attendances, to assess progress should be at the Breast Unit, not at the Cancer Centre.
- This should be supported by a clinical nurse specialist (see section on the breast care nurse—above).

Radiotherapy

Avoidance of delay. In the case of early breast cancers treated by wide local excision and post-operative radiotherapy, the time interval between the two should not exceed 4 weeks (except for clinical reasons).¹⁶ The precise time should be determined by clinical assessment and should take into account any time needed for wound healing. Good practice, to secure quick referral, is to hold combined clinics with the surgeon.

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.

Radiotherapy techniques. Radiotherapy techniques should be directed by the radiotherapist who is a member of the Breast Team and who is seeing the majority of breast cancer patients from that unit.

Therapeutic radiographers should be appropriately trained, and note taken of the College of Radiographers recommended baseline staffing levels for the safe use of megavoltage machines.¹⁵

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.

Because the endocrine treatments were historically ablative, the surgeon has 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 Advanced Breast Clinic.

- Where local protocols for adjuvant or advanced systemic therapies take note of Oestrogen Receptor (ER) content, this result must be made available to the Breast Team.

Chemotherapy

Avoidance of delay. 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 cases from that unit. The effective delivery of these regimes 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 anti-cancer 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. Staff must be aware of, and GPs must be given 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.

Expected demand and timetable consequences for surgeons

The estimate here is for the surgical workload for a Breast Unit in a District General Hospital which covers a 300,000 population. It is assumed that individual breast surgeons will pool their clinics and cases to work within the Breast Unit and that the surgeons will also provide the surgical input to the local Breast Screening Unit (see Guidelines for Surgeons in Breast Cancer Screening). The report of the British Breast Group suggests that around 200 Breast Units are needed to cover the UK. However, detailed inspection of two Regions indicates that there are likely to be few Breast Units outside of the present screening units (120) which would mean covering around 400,000 population per Breast Unit.

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. Together with the screen-detected cases this will generate around 150 new carcinomas per annum. Not all the carcinomas will require surgery because of age or advanced nature but at least two cases per week will require standard surgery for primary breast cancer. Some cases will require lengthier procedures, e.g. for extensive local disease or reconstruction. Added to this there are cases of loco-regional recurrence, breast lumps and mammographic lesions for diagnostic biopsy and benign breast conditions causing symptoms requiring operation (such as mammillary fistula). This load will require three operating lists per week. The total number of surgical sessions to be carried out by a specialist trained in breast disease are estimated below. These sessions should be carried out by trained specialists (at consultant or associate specialist level) or by level III trainees (see Table 4).

Fixed sessions

- To see 40 new patients 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, e.g. 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). Surgeon together with the clinical oncologist on the Breast Team. Extra support is required for this clinic (and much of the work can be carried out by registrar or clinical assistant but the surgeon needs to be available for consultation = *half session of surgical time*). Again imaging facilities must be available.
- *One* screening Assessment Clinic held weekly. The Screening Assessment Clinic session should include a screening meeting (attended by surgeon, radiologist and pathologist from the breast team). Around 20 cases are likely to be seen in one Assessment Clinic.
- Combined Advanced/Recurrent Breast Clinic held weekly. Attended by surgeon in addition to the clinical oncologist (\pm 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 consultant (= *half session per week*).
- Clinic for a number of conditions not covered by the above, e.g. symptomatic benign problems (\equiv *half a surgical session*).
- Sessional time to explain, with the help of the breast care nurse, the diagnosis of cancer and the treatments to be employed ('Results' clinic) (\equiv *half a surgical session per week*).

The overall fixed surgical sessional commitment is thus 8 *breast sessions made up of 6 clinic sessions and 3 operating*. 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.

Non-fixed component

Within the contract for the breast surgeon (non-fixed sessional component) should be attendance at a weekly Multidisciplinary Meeting, with the Pathologist and Clinical Oncologist from the Breast Unit to consider the ongoing treatment of the patients recently operated upon and time for breast audit (= 1 session on breast disease); *remaining sessions to cover ward rounds and emergency and on-call commitment for 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.

Continuing education

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 specialty association of Breast Surgeons will allocate points upon inspection of the programmes, symposia and specific training courses directed at breast disease. The meetings secretary of the Breast Surgeons Group has already arranged annual study days for surgeons in breast disease and will continue to do so.

Audit

A number of computer-based data recording systems have been designed (e.g. the Salem system, the King's system).

Table 18.

Quality objectives	Outcome measures
To encourage the entry of patients into clinical trials	The numbers of patients suitable for and entered into clinical trials should be recorded

The BASO group will endeavour to ensure comparability of the data recorded in these.

Every hospital receives money for audit. The Breast Surgeon should ensure that data on diagnosis and treatment of breast disease receive adequate clerical support from this budget.

Each Unit must be able to provide results of audit of its surgical data for purchasers on at least an annual basis.

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. 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.¹⁷

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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 December 1996.

The sections on radiography, radiology, pathology, breast care nursing and chemotherapy were contributed by the specialists in these disciplines who serve as representatives on the National Surgical Co-ordination Group for Breast Screening.

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