

# The requirements of a specialist Breast Unit

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## 1. Introduction

In October 1998 in Florence the First European Breast Cancer Conference took place, jointly organised by the European Organization for the Research and Treatment of Cancer Breast Cancer Cooperative Group (EORTC-BCCG), the European Society of Mastology (EUSOMA) and Europa Donna. Delegates agreed a consensus on research, genetic predisposition, psycho-social status, treatment and notably quality of care. 'The Florence Statement'<sup>(1)</sup> demanding that all women have access to multidisciplinary breast clinics based on populations of around 250,000; also it called for mandatory quality assurance programmes for breast services. With the intention of assuring a high quality specialist service Europe-wide, a working party was established to consider what should comprise a specialist service. These resulted in the publication of The 'Requirements of a Specialist Breast Unit', which represents the opinion of the European Society of Mastology (EUSOMA) and EORTC on the standards required for forming high quality Breast Units across Europe<sup>(2)</sup>.

These Guidelines have been generally well received and have been influential in the introduction of the multidisciplinary working in several countries. 'The Brussels Statement'<sup>(3)</sup>, following EBCC2 drew attention to these guidelines and demanded that processes of accreditation of breast units be implemented. The importance of the establishment of multidisciplinary breast units was again stressed in 'The Hamburg Statement'<sup>(4)</sup>, which followed EBCC4. Attention was drawn to the approval given to this in the European Parliament (OJ C 68 E (18.03.2004), p.611).

## 2. Objectives

To make available for all women in Europe a high quality specialist Breast Service.

To define the standards for such a service.

To recommend that a means of accreditation and audit of Breast Units be established in order that units providing this service should be recognisable to patients, practitioners and health authorities as being of high quality.

## 3. Background

In the UK the recommendations of the report 'A Policy Framework for Commissioning Cancer Services'<sup>(5)</sup> were that specialist breast units be established, staffed by clinicians and other professionals specialising in single 'anatomical areas', such as in the breast. A number of reports from groups concerned in the management of breast disease were published, by the British Breast Group<sup>(6)</sup>; by the Breast Specialty Group of the British Association of Surgical Oncology (BASO)<sup>(7, 8)</sup> and by the UK NHS Executive<sup>(9)</sup>. The European Society of Surgical Oncology (ESSO) has published similar guidelines<sup>(10)</sup> to those of BASO and European Guidelines for Quality Assurance in Mammographic Screening have been published<sup>(11)</sup>. All these reports recommend that breast disease be cared for by specialists in breast disease working as teams in Breast Units.

Across Europe an increasing number of well organised multidisciplinary Breast Units have been established but overall the quality of each service is variable. It is the hope of those working in the field that the recommendations in this report will become mandatory thus building a breast cancer service of the highest quality throughout Europe.

In order that this may be assured it is necessary that standards are set which any hospital wishing to form a recognised Breast Unit must meet.

Further EUSOMA working parties have made recommendations to establish quality standards in the separate aspects of breast cancer care and have published Guidelines on diagnosis, local treatment of the primary tumour, management of risk and reconstruction, endocrine therapy and radiotherapy<sup>(12, 13, 14, 15, 16)</sup>

## 4. General recommendations

### Definitions

Unit: Essentially a group of specialists in breast cancer and need not necessarily be a geographically single entity, although the separate buildings must be within reasonable proximity, sufficient to allow multidisciplinary working

Clinic: used to mean a session, usually around 3 hours at which a number of patients are seen for clinical examination and investigations

Specialists: completed training and certified in own discipline (e.g.) Surgery, Radiology etc and for Core Team members, spending half their working time (clinics, operating, pathology or imaging reading, multidisciplinary meetings, inpatient care etc in breast cancer)

Radiologist: a specialist in imaging for diagnosis

Radiographer: a technician, taking the mammograms and responsible for mammographic quality

Radiation Oncologist: specialist in radiotherapy only

Medical Oncologist: specialist in medical oncology

Breast Care Nurse: qualified nurse, trained to give psychological support to breast cancer patients (especially at the time diagnosis is given) and to act in follow up as link between patient and breast Team

Psychiatrist: medically qualified specialist in pharmacological treatment of patients with psychiatric and psychological problems

Psychologist: not usually medically qualified and therefore unable to prescribe pharmacological therapies

Surgeon: gynaecological surgeons specialising in breast cancer are included in this term

- 4.1 Recognition of a Breast Unit must be based on mandatory requirements.
- 4.2 A European process of voluntary accreditation of Breast Units, based on the fulfilment of mandatory requirements should be established. To give uniformity a standard database should be made available.
- 4.3 Units must record the basic data on diagnosis, pathology, primary treatment and clinical outcomes. The data must be available for audit and the Unit team should hold regular audit meetings inspecting separate topics and designing and amending protocols and QA systems. These meetings must be minuted. Performance and audit figures must be produced yearly and set alongside defined quality objectives and outcome measures, such as those laid down in the EUSOMA Guidelines on the various aspects of care<sup>(12, 13, 14, 15, 16)</sup> or in other suitable guidelines.
- 4.4 The Unit must have written protocols for diagnosis and for the management of cancer at all stages (primary and advanced cancer). All protocols must be agreed upon by the core team members. New protocols and protocol amendments should be discussed by the core team at the audit meetings (see 4.3).
- 4.5 Breast Units will most often be established in large or medium sized hospitals; they should generally cover one-quarter to one-third of a million total population. Some highly specialised units will be larger.

- 4.6 Population Breast Screening programmes should be based within or be closely associated with a recognised Breast Unit and not work as a separate service. The radiologists, surgeons and pathologists working in the screening programme must be core members of the associated Breast Unit.
- 4.7 There has to be a minimum size for a Breast Unit from the point of view of numbers of specialist staff required, arrangement of frequent clinics, provision of equipment and cost-effectiveness. If two hospitals are close together it is more practical for only one of them to establish a functional breast unit serving both hospitals, i.e., the breast team works at both centres.
- 4.8 Breast Unit should hold outreach clinics for symptomatic referred women, screening assessment and follow-up, in the smaller hospitals in the neighbourhood if these are at a distance from the Breast Unit. In areas with low population density, out-reach arrangements are preferable to the establishment of small Breast Units without the clinical volume to allow expertise. In that circumstance outreach clinics may be only held as infrequently as once per month; such scheduling may prolong waiting times for appointments but clinical evaluation by an expert team is considered preferable to maintaining short waiting times.
- 4.9 Breast Units must provide care of breast disease at all its stages - from screening through to the care of advanced disease. Occasionally the patient may need to be sent to an associated large oncology centre for radiotherapy but the patient must essentially be managed and followed-up at her Breast Unit.
- 4.10 Breast Units should manage their own budget, covering all the work of the unit.

## **5. Mandatory requirements**

### **5.1 Critical mass**

A Unit must be of sufficient size to have more than 150, newly diagnosed cases of primary breast cancer (at all ages and stages) coming under its care each year. Note: these are newly diagnosed breast cancers. They may have been diagnosed elsewhere but if they have received any prior treatment and have been transferred, for example, to receive radiotherapy, they should not be counted.

All primary treatment must be carried out under the direction of the Unit (operation must be in the unit, adjuvant therapies must be directed by the unit but may have been received in other settings e.g. RT and chemotherapy). Follow up should be under the control of the Unit.

The reason for recommending a minimum number is to ensure a caseload sufficient to maintain expertise for each team member and to ensure cost-effective working of the Breast Unit: the establishment of a clinic staffed by experts is expensive and must have a high through-put of patients.

A number of Units will be recognised as teaching centres, nationally or internationally. They may be recognised for teaching overall breast cancer management or special aspects (e.g.) screening, reconstruction, pathology.

### **5.2 Core team**

Each member of the core team must have special training in breast cancer. Each member of the breast unit core team must undertake continuing professional education on a regular basis. Breast Unit budgets must include provision for this.

5.2.1 The Breast Unit must have an identified Clinical Director of Breast Services.

### 5.2.2 Breast Surgeons (including Gynaecologists performing breast surgery)

Two or more nominated surgeons specially trained in breast disease, each of whom must personally carry out the primary surgery on at least 50 newly diagnosed cancers per annum and must attend at least one diagnostic clinic per week. For an average sized unit the surgeons will need at least eight identified ca. 4 hr sessions per week in Breast Disease. These sessions will allow for operating time, participation in diagnostic clinics, a follow-up clinic and, where appropriate, screening assessment clinics. A session must be allowed for attendance at a weekly team case management and audit meeting. A Unit team must provide breast surgical reconstruction when required for those patients not suitable for breast conserving therapy and be able to apply special techniques for patients with extensive local disease. The breast surgeons in the team should be able to undertake basic reconstruction or recontouring and there should be a standard arrangement or joint reconstruction clinic with one or two nominated Plastic Surgeons (non-core team member) who take a special interest in breast reconstructive and recontouring techniques.

### 5.2.3 Breast Radiologists

There must be at least two nominated radiologists, fully trained and with continuing experience in all aspects of breast disease and associated imaging, tissue sampling and localisation procedures under image control. Ideally any radiologist investigating breast patients should participate in the screening programme in countries in which this is established and must participate in a national or regional QA scheme. They must fulfil the volume requirements as laid down for breast assessment in Chapter 5 and the previously published document 'Quality Assurance in the Diagnosis of Breast Disease'<sup>(12)</sup>, reading a minimum of 1000 mammograms per year (5000 for those participating in a screening programme). They must attend multidisciplinary meetings for case management and audit purposes. They must be present in diagnostic assessment clinics with the surgeon. Each radiologist must attend at least one diagnostic clinic per week for symptomatic patients or screening assessment.

### 5.2.4 Breast Pathologists

A lead pathologist plus usually not more than one other nominated pathologist, specialising in Breast Disease, will be responsible for all breast pathology and cytology. Pathologists carrying out these roles must have contractual sessions to attend team case management and audit meetings. They must be familiar with national and/or European performance quality standards and guidelines. They must take part in available European, National and Regional quality assurance schemes.

### 5.2.5 Breast Oncologists

(a) A nominated radiation oncologist must arrange the appropriate delivery of radiotherapy<sup>(16)</sup>. He/she must hold advanced disease clinics with other members of the breast team at the Breast Unit and must take part in the case management and audit meetings of the Unit.

(b) In some countries, Clinical Oncologists carry out both radiation therapy and prescribe the chemotherapy. In centres in which a Medical Oncologist gives the chemotherapy he/she should be a member of the core team and take a full part in case management and audit meetings.

### 5.2.6 Breast Diagnostic Radiographers (Technicians)

Radiographers with the necessary expertise and training in mammography are essential members of the team. They must fulfil the training and working practice recommendations. They must be responsible for taking the mammograms, which must not be performed by radiographic or non-radiographic personnel without the above training.

### 5.2.7 Data Managers

There must be a system covering audit. A data manager must enter data on diagnosis, treatment, pathology and clinical outcomes contemporaneously.

### 5.2.8 Patient Support staff

Regular support (advice, counselling, psychological help) is given by Breast Care Nurses in some countries and psychologically professionally trained persons with expertise in Breast Cancer in others. These persons must be members of the core team. They must be available to counsel and offer practical advice and emotional support to newly diagnosed patients at the time the diagnosis is given, so as to further explain treatment plans. They should also be available on demand from patients in the Primary Breast Cancer Follow up clinic and in the Advanced Breast Clinic. Particularly they must be present to support women when the diagnosis is given that the disease has become advanced. At least two Breast Care Nurses are needed per breast unit.

## 6. Equipment

6.1 The unit must be in possession of all necessary imaging equipment for complete and adequate breast diagnosis

6.2 The minimum equipment in a department giving radiotherapy must be two megavoltage units, a brachytherapy unit, a simulator and a computerised planning system. The department must have a radiotherapeutic quality control programme for breast cases.

## 7. Facilities/Services

Clinics (see definition in Section 4). Consultations for Breast patients should be held separately, i.e., not as part of general surgery.

### 7.1 New patient clinics

At least one clinic per week for newly referred symptomatic women must be held. A Unit diagnosing 150 new cancers per year must expect over 1500 new referrals of symptomatic women (= approximately 30 per week).

A suggested good practice is that all newly referred women with breast symptoms should be offered an appointment within 10 working days of receipt of the referral.

Clinics to which patients are referred or self-referred must be staffed by a surgeon, a radiologist and radiographers from the breast care team. Multidisciplinary working must allow all standard investigations for triple assessment (clinical examination and all appropriate imaging and tissue diagnostic procedures) to be completed at one visit. Where possible the finding of no abnormality or a confirmed diagnosis of a benign lesion should be communicated to the patient at that visit.

### 7.2 Communication of the Diagnosis and Treatment Plan

It may not be possible (now that core biopsy is most often used) or may not be considered appropriate by the unit to give the diagnosis of cancer at the initial visit. Women found to have breast cancer should receive that diagnosis within 5 working days.

The diagnosis should be ideally communicated personally by the surgeon: if it is communicated by the radiologist, then the surgeon ( $\pm$ ) the oncologist must personally advise the patient on treatment. It is recommended that a breast care nurse (or) psychologically trained person (see 5.2.8) be present to discuss fully with the patient the options for treatment and to give emotional support. If a patient has

clear advanced breast cancer it may be more appropriate that an oncologist rather than a surgeon gives the diagnosis if the patient's treatment does not involve surgery.

A suitable room with sufficient privacy must be available. In units in which preoperative irradiation or primary medical therapies are used, cases which might be suitable for these should be seen jointly by a surgeon and radiation or medical oncologist before treatment commences.

A diagnosis should not be given to a patient by letter or on the telephone, unless at the specific request of the patient given adequate and full informed choice.

### 7.3 Multidisciplinary Case Management Meetings (MDM's)

All members of the core team must attend the Multidisciplinary Meeting (MDM), which must be held at least weekly. The following should be discussed:

- cases in which the diagnosis is as yet uncertain e.g., following core biopsy
- cases in whom the diagnosis of cancer is confirmed and who may be considered for primary medical therapy
- all cases following surgery on receipt of the histopathology for discussion of further care and
- cases in follow-up who recently have undergone diagnostic investigations for possible symptoms of recurrent or advanced disease

It is possibly more convenient to have two MDM's per week:

- one for cases in diagnosis attended by surgeons, radiologists and pathologists and
- one for post-operative consideration of prognosis and adjuvant therapies and for cases investigated for disease recurrence (oncologists, surgeons, radiologists and pathologists)

### 7.4 Physiotherapy

Physiotherapy must be available for the post-operative recovery period to ensure good shoulder mobility, etc.

### 7.5 Adjuvant Therapies

- The multidisciplinary team (MDT) must decide on the appropriate adjuvant therapies in light of the pathology of the surgical specimen.
- Radiotherapy may be delivered within the same hospital or patients may have to travel to a Radiotherapy Unit in another Hospital (at which the core team radiation oncologist must be able to supervise their treatment).
- The administration of cytotoxic therapy as adjuvant therapy or for advanced disease must be by an accredited oncologist (member of the core team) with proper facilities. Cytotoxic therapies may be given in another hospital but the decisions regarding their application must be made by the MDT of the Unit.

### 7.6 Advanced and Recurrent Breast Cancer

-There must be one Advanced Breast Cancer Clinic at least every 2 weeks at the Breast Unit, separate from the general oncology clinics (although sometimes combined with gynaecological oncology) and attended by the Clinical Oncologist ± Medical Oncologist (see 5.2.5 b). The surgeon must be available if required for consultation and must be in full attendance if the breast surgeons supervise the endocrine

therapies. Patients with distant metastases locally advanced primary breast cancer and local or regional recurrence, must be managed in this clinic according to protocols agreed by the multidisciplinary team. Patients who have received radiotherapy or chemotherapy at another Cancer Centre should normally be referred back to the Breast Team at their Breast Unit for further follow-up and decision making in the Advanced Breast Cancer Clinic.

-A palliative care/pain control service must be easily accessible.

#### 7.7 Follow-up of primary breast cancer

-All patients with primary breast cancer must be followed-up in a Clinic directly supervised by one of the surgeons. Any necessary imaging or other investigations should be carried out at the same visit.

-Although the patient may have to visit a separate Hospital to receive radiotherapy or specialised chemotherapy, the decisions on the case management and the subsequent follow-up should be by the team members of her Breast Unit. The skills of the diagnostic breast team are then available for the detection and investigation of a possible recurrence.

#### 7.8 Benign disease

The Breast Unit must also advise and where necessary treat women with benign disease (e.g.) cysts, fibroadenoma, mastalgia, inflammatory conditions, mammillary fistula and phyllodes tumour.

#### 7.9 Family History/genetics

Advice is best given in a multidisciplinary clinic, the specialists involved are a clinical geneticist and from the team a breast surgeon with reconstructive skills, radiologist and psychiatrist or clinical psychologist. Gene probing must be available when required and ideally a molecular geneticist should be accessible for consultation by the specialists in the clinic.

#### 7.10 Reconstruction

(See 8.2 below)

#### 7.11 Breast Screening

Ideally breast screening centres should be a part of Breast Units and the same radiologists should be members of the Unit team and work in screen detection and the diagnosis of symptomatic disease. Assessment centres should be placed in Breast Units.

#### 7.12 Patient Information

Women must be offered clear written and oral information regarding their diagnosis and/or treatment options. The Breast Unit should also provide written information concerning local out patient support groups and advocacy organisations and should also respect the patients rights as outlined in the Breast Cancer Resolution of the European Parliament (OJ C 68 E (18.03.2004), p.611). Patients should be provided with a list of their rights as outlined in the breast cancer resolution

### **8. Associated Services and non-core personnel**

These are services for which it cannot be expected that staff will spend the majority of their time on breast disease.

### 8.1 Extra Psychological Support

If the patient is experiencing psychological morbidity that cannot be dealt with effectively by members (usually breast care nurse or psycho-oncologist) of the Unit team, she should be referred to a psychiatrist with whom there are particular arrangements to see breast patients for the Breast Unit (non-core team member).

### 8.2 Plastic Surgeon

The Breast Unit should make arrangement with one or two nominated plastic surgeons with a special interest in breast reconstructive and recontouring techniques.

### 8.3 Geneticists

Women seeking advice with regard to risk, e.g., family history, must be able to receive advice from the Breast team, which must include a clinical geneticist with a specialist interest in breast cancer (see 7.9).

### 8.4 Palliative Care

A specialist palliative care service must be available for the referral of patients with advanced breast cancer. A close working relationship must be established between members of the Breast Unit (especially the breast care nurse) and the palliative care service to ensure that breakdowns in continuity of care do not occur and also with the local network for home assistance.

### 8.5 Prosthesis

There must be provision for a Prosthesis fitting service within the unit.

### 8.6 Physiotherapy and Lymphoedema

An identified Physiotherapist or a Breast Care Nurse for the treatment of lymphoedema and late sequelae.

## 9. Research

Research is one of the essential parts of training of specialists. As part of Audit Units must record numbers of patients entered into clinical trials and details of all other research. Units should be encouraged to provide research opportunities and this must be taken into account when assessing units for their suitability for accepting trainees.

## 10. Teaching

The Unit must provide teaching, whether simply for junior staff or for students or on a national or international basis. Some units may particularly concentrate on certain areas (e.g.) Reconstruction, Screening, Pathology, etc.

## 11. Additional points

The implementation of the suggested structure of Breast Units requires a reorganisation of time in each discipline, so that as a consultant spends more time in breast disease, his or her colleagues no longer treat breast cancer and specialise in other areas. Rationalisation of work patterns, in this way would provide sufficient staff for the Breast Units. Such a move would coincide with changes that are already occurring within all disciplines, for example, from General Surgery the emergence of specialist surgeons for urology, microinvasive techniques, vascular surgery, upper GI, hepatic and colon. All

work must be carried out or directly supervised by specialists specifically trained in breast disease. A service provided by a trained specialist is more efficient and more cost effective – diagnostic decisions are made earlier whereas junior staff are more likely to call a patient back several times unnecessarily and to carry out unnecessary investigations; operating by consultants gives better results for technical reasons; the interpretation of imaging techniques and the reading of histology is much more likely to produce definitive opinions if carried out by experts. We estimate that for a 10 million total population base 30-40 Breast Units are required for the ideal service and that reorganisation in this way will provide considerable financial savings. This could easily be achieved and should be attractive to many countries.

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