



# The requirements of a specialist breast unit

## 1. Introduction

In October 1998 in Florence the First European Breast Cancer Conference took place, jointly organized 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<sup>(5)</sup>.

A European process of voluntary certification of Breast Units, based on the fulfillment of mandatory requirements should be established. To give uniformity a standard database should be made available.

## 2. Objectives

To make available to all women in Europe a high quality specialist Breast Services.  
To define the standards for such services.

To recommend that a means of voluntary certification 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>(6)</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>(7)</sup>; by the Breast Specialty Group of the British Association of Surgical Oncology (BASO)<sup>(8, 9)</sup> and by the UK NHS Executive<sup>(10)</sup>. The European Society of Surgical Oncology (ESSO) has published similar guidelines<sup>(11)</sup> to those of BASO and European Guidelines for Quality Assurance in Breast cancer Screening and diagnosis have been published<sup>(12)</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 organized 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 recognized 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,<sup>(13, 14, 15, 16, 17,18)</sup> endocrine therapy and radiotherapy.

The implementation of the suggested structure of Breast Units requires a reorganization of time in each discipline, so that as medical specialists spend more time in breast disease, his or her colleagues no longer treat breast cancer and specialize in other areas. Rationalization 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, micro invasive 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 trained specialists is more efficient and more cost effective. We estimate that for a 10 million total population base 30-40 Breast Units are required for an ideal service and that reorganization in this way will provide considerable financial savings while also delivering high quality breast care. This could easily be achieved and should be attractive to many countries.

## 4. Definitions

Unit: A group of specialists in breast cancer 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, at which a number of women/patients are seen for clinical examination and/or investigations, counseling, etc.

Specialists: completed training and certified in own discipline (e.g.) Surgery, Radiology etc and for Core Team members, spending consistent part of their working time (clinics, operating, pathology or imaging reading, radiation oncology, systemic treatment, multidisciplinary meetings, inpatient care etc ) in breast cancer (see section on the different specialties)

Radiologist: a specialist in imaging for diagnosis

Radiographer: a technician, taking the mammograms and committed to achieving mammographic quality

Radiation Oncologist: specialist in radiation oncology only

Medical Oncologist: specialist in medical oncology

Clinical Oncologist: in some countries clinical oncologists carry out both radiation therapy and Medical Treatment.

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: dedicated to the psychological support to patients. Not usually medically qualified and therefore unable to prescribe pharmacological therapies

Surgeon: gynecological surgeons specializing in breast cancer are included in this term

Data manager: a trained and dedicated person responsible for data management

## 5. General requirements

### Critical mass

A Unit must be of sufficient size to have at least 150 newly diagnosed cases of primary breast cancer (at all ages and stages) coming under its care each year.

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 agreed at the MDM by the unit but may have been received in other settings e.g. RT and chemotherapy).

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.

### Clinical Director

The Breast Unit must have an identified Clinical Director of Breast Services, a MD from any specialty of the core team who is responsible of the coordination of Unit.

### Protocols

The Unit must have written protocols for the diagnosis and 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 must be discussed and formally recorded by the core team at the audit meetings.

### Audit

Unit must have a database for audit purpose. Data that should be recorded in database are: source of referral (screening programme, spontaneous screening, symptomatic) diagnosis, pathology, primary treatment and clinical outcomes. The Unit should also participate in an external bench marking activity. The Unit team must hold at least one yearly audit meeting, using data for inspecting separate topics and designing and amending protocols and QA systems. A formal record of these meetings must be kept.

Regarding performance the Unit must achieve the minimum outcome for mandatory QI as indicated by Eusoma, or take appropriate corrective measures.

If screening is part of the service, the Unit should record whether a case is screen detected or is an interval case and document this information in the audit system accordingly and have ongoing contacts with other screening centers in its area.

Unit must formally identify a data manager, with responsibility for ensuring that all relevant data are collected (contemporaneously or retrospectively), recorded and analyzed.

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

MDMs must be held at least weekly and must be minuted. The Unit must discuss at least 90% of cases. All members of the core team (radiologist, pathologist, surgeon, reconstructive surgeon, radiation oncologist, medical oncologist, Breast care nurse) should attend the Multidisciplinary Meeting (MDM). It is recommended that these MDMs include discussion of patients that undergo diagnostic breast needle biopsy, as well as cases where treatment planning is being considered.

### Screening

Population Breast Screening programmes should be based within or be closely associated with a recognized Breast Unit. The radiologists, surgeons and pathologists working in the screening programme must be core members of the associated Breast Unit. 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.

### Communication of the Diagnosis , Treatment Plan and waiting time

It may not be possible (now that core biopsy is most often used) to give the diagnosis of cancer at the initial visit. It should be recommended to give the diagnosis to the patient as soon as possible. Patients should commence the primary treatment within 4 weeks from the definitive diagnosis.

The communication to the patient can be preliminary given by each specialist according to his/her competence, but following the appropriate MDM discussion to plan the treatment, the results should be given to the patient by one clinician.

It is recommended that a breast care nurse (or) psychologically trained person be present to discuss fully with the patient the options for treatment and to give emotional support. Each patient has to be fully informed on each step of the diagnostic and therapeutic pathway and must be given adequate time to make her decision.

A suitable room with sufficient privacy should be available. <sup>(9)</sup>

A positive 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.

### Patient Information

Women must be offered clear oral and written information (leaflets) regarding diagnosis and treatment options. It is recommended that these leaflets are personalized by the Breast Unit. The Breast Unit should also provide written information concerning local out patient support groups and advocacy organizations and should also respect the patients rights as outlined in the Breast Cancer Resolution of the European Parliament <sup>(5)</sup>. It is recommended to provide patients with a list of their rights as outlined in the breast cancer resolution.

### Teaching

The Unit should 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. The Unit should organize one teaching course a year at local or national level.

### Research

Research is one of the essential parts of training of specialists. The Unit should record numbers of patients entered into clinical trials and details of all other research.

## **6. Breast surgery and reconstructive surgery**

There must be at least two nominated specialist breast surgeons (including Gynecologists performing breast surgery) specially trained in breast disease, each of whom must personally carry out the primary surgery on at least 50 newly diagnosed cancers per annum.

To be breast dedicated the surgeon has to spend at least 50% of his/her working time in breast disease. This will allow for operating time, participation in diagnostic clinics, new patient clinics, follow-up clinics and audit meetings.

Surgeons and plastic surgeons should participate in MDMs

The breast surgeons in the team should be able to undertake basic reconstruction, when required, and oncoplastic surgery.

Training for Breast Surgeons should comply with what indicated in the Eusoma guidelines on training for specialized Health Professionals<sup>(19)</sup>.

At the Unit sentinel lymph node procedure must be available.

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

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

## **7. Breast Radiology**

There must be at least two nominated specialist breast radiologists.

Any radiologist investigating breast patients should participate in the screening programme in countries in which this is established and participate in a national or regional QA scheme. The radiologist must read a minimum of 1000 mammography cases per year (5000 for those participating in a screening programme is recommended)<sup>(12)</sup>. To be considered breast dedicated, a radiologist must spend at least 30% of the time in breast disease.

Each radiologist must attend at least one diagnostic clinic per week for symptomatic patients or screening assessment, and audit meetings. They should participate in MDMs.

Training for Breast Radiologist should comply with what indicated in the Eusoma guidelines on training for specialized Health Professionals<sup>(19)</sup>.

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

*Mammography Unit (preferable digital)*

*Stereotactic biopsy attachment and/or dedicated prone biopsy table*

*Ultrasound equipped with a small part probe  $\geq 10\text{MHz}$*

It is recommended that this equipment is not older than 10 years.

Quality control of all equipment used for breast imaging must be routinely performed, according to the relevant national protocols and/or the European Guidelines.<sup>(12)</sup>

The Unit must be able to perform the following examinations:

*Clinical examination*

*Diagnostic mammography*

*Ultrasound of the breast and axilla*

*Core biopsy (free-hand US guided and X-ray guided )*

*Breast MRI (if not available within the hospital, the Unit must have in place an agreement with a local diagnostic service that provides breast MRI as recommended by EUSOMA standards)*

The unit may also be able to perform:

*Freehand and image guided FNAC, (core biopsy is considered to be the preferred technique for tissue sampling but FNAC may be used as an alternative where core biopsy is not possible and as the primary technique for sampling the axilla) CB vacuum assisted, Vacuum assisted mammotomy (VAM – image guided (ultrasound/x-ray/MRI guided)*

It is recommended that a formal imaging risk classification is used (eg BIRADS™, European Classification).

Breast Diagnostic radiographers must be responsible for performing the mammograms. The Unit must have at least 2 radiographers, each performing at least 20 mammograms per week <sup>(12)</sup>.

The training for Diagnostic radiographers should comply with what indicated in the Eusoma "guidelines on Standards for the training for specialized Health Professionals dealing with Breast Cancer.

They should also attend refresher courses at least every 3 years <sup>(12)</sup>. It is recommended that radiographers follow the working practice recommendations defined in the European Guidelines<sup>(12)</sup>. (E.g.: positioning, Quality control, etc).

Radiographers should participate in audit of their daily performance (retake analysis). They should have a clear understanding of the requirements of technical quality control on a day to day basis and should perform the daily quality control, sensitometry and phantom test, for analogic mammographer <sup>(12)</sup> and weekly phantom test for digital mammographer.

## **8. Breast Pathology**

The Unit must have a lead pathologist plus an additional one or two depending on the Unit size. They should be responsible for all breast pathology and cytology.

To be breast dedicated a pathologist must spend approximately 25% of his/her working time in breast disease.

All specialist pathologists reporting breast cancer should see at least 50 primary breast cancer resections per year.<sup>(20)</sup>

They should take part in available European, National and Regional quality assurance schemes. Pathologists must attend audit meetings. They should attend MDM.

Training for Breast Pathologists should comply with Eusoma guidelines on training for specialized Health Professionals.<sup>(19)</sup>

The Service must be equipped with: processors, microtomes, staining machines and immunostainers which should be not older than 10 years and well maintained.

With regard to workup of the specimen, items included in the report, nomenclature, special studies (Immunohistochemistry for diagnosis, Immunohistochemistry for ER +/- PR, access to her2 testing), the laboratory should refer to European Guidelines.<sup>(12)</sup>

For core biopsy the unit must use B-classification.

It is recommended to show histology at MDM, preferably direct from slides.

The laboratory should keep at least 10 years slides archived (2 years on site) and report for 25 years minimum or following the relevant national protocols if available.

Pathologists should be familiar with national and/or European performance quality standards and guidelines.

Double reading is not mandatory.

## **9. Breast Medical Oncology**

The unit must have a medical oncologist dedicated to breast cancer, spending around 40% of working time in breast cancer. He/she must attend audit meetings, advanced breast cancer clinics and other clinics (loco-regional, recurrent ).

He/she should attend MDMs.

Supervision of systemic therapies and or decision making process for adjuvant and neo-adjuvant treatments should be in accordance with local/institutional rules and supervised by the designated medical oncologist.

The Unit should aim to enroll at least 10% of all patients in clinical trials.

Training for Breast Medical Oncologist should comply with Eusoma guidelines on training for specialized Health Professionals <sup>(19)</sup>.

If Medical Oncology Unit is not available within the hospital, the Breast Unit must have an agreement with a medical oncology unit and the medical oncologist should attend MDMs at the Breast Unit.

Outcome information on all patients treated with a systemic therapy should be collected even if patients are treated elsewhere.



## **10. Breast Radiation Oncology**

The Unit must have a nominated radiation oncologist dedicated to breast cancer.

He/she must attend audit meeting and advanced breast cancer clinics and other clinics: e.g. loco-regional, recurrent. He/she should attend MDMs.

To be breast dedicated the radiation oncologist must spend at least 30% of their clinical time in breast disease. Training for Radiation Oncologists should comply with Eusoma guidelines on training for specialized Health Professionals <sup>(19)</sup>.

The minimum equipment in a department giving radiotherapy must include at least two megavoltage units, a simulator (preferably a CT simulator) and a computerized 3D planning system. The department must have a radiotherapeutic quality control programme for breast cases. The Unit must also have a quality control programme, and perform the verification of the linear accelerator output. They Unit must also take measures to protect the lung and heart: preferably 3D dose volume histograms.

Experience in special techniques such as IMRT, partial breast irradiation, gating, 3D brachytherapy is recommended.

Radiotherapy may be delivered within the same hospital or patients may have to travel to a Radiotherapy Unit in another Hospital. If the Radiotherapy Unit is not available within the hospital, the Unit must have an agreement with a radiotherapy service and the radiation oncologist should attend MDMs at the Breast Unit.

## **11. Breast Care Nursing**

At least two Breast Care Nurses are needed per breast unit.

Training for Breast Care Nurses should comply with the Eusoma "guidelines on Standards for the training for specialized Health Professionals dealing with Breast Cancer" and EONS core curricula for Breast Care Nurses. <sup>(20, 22)</sup>

A Breast Care Nurse must dedicate at least 30% of his/her working time to breast disease. Breast care nurses should attend MDMs.

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 that the disease has become advanced is given.

## **12. Other services**

### Clinics

All consultation for Breast disease must be done in dedicated clinics.

### Clinical genetics clinic

The Unit must have a clinical geneticist with a special interest in breast cancer. Units that are not running a genetic service must have in place an agreement with an hospital where the service is available.

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, gynecologist, radiologist and psychiatrist or clinical psychologist.

The patient data from these clinics should be formally recorded in an appropriate data base and this team should be actively involved in research.

Genetic testing (for BRCA mutation) must be available when required and a molecular geneticist should be accessible for consultation by the specialists in the clinic.

Risk assessment counseling and DNA testing for BRCA mutations in selected high risk group should be offered, in accordance with unit protocols.

The clinical genetics service should offer:

#### *Mutation analysis*

Genetic testing should include complete sequencing of coding regions, either directly or after a screening method. Specific techniques to detect duplications or deletions of one or more exons may be indicated. <sup>(22)</sup>.

#### *Diagnostic Surveillance*

Unit should have written protocols where diagnostic surveillance is specially considered for high risk women including screening MRI according to the risk level.

#### *Other intervention*

The unit should have a written protocol for prophylactic operations and chemoprevention.

#### *Psychological support:*

Psychological support should be given to patients when necessary to adjust them to the situation, to help them to cope with stress and to support their individual decision-making<sup>(23)</sup>.

### New patient clinics

At least one clinic per week for newly referred symptomatic women must be held.

Clinics to which patients are referred or self-referred must be staffed by a surgeon or a radiologist from the breast care team. Multidisciplinary working should allow all standard investigations for triple assessment (clinical examination and all appropriate imaging and tissue diagnostic procedures) to be completed at one visit.

### Advanced Breast Cancer Clinics

Advanced Breast Cancer patients must be seen within Breast Unit. These clinics must be separate from the general oncology clinics and attended by the Medical Oncologist and the Radiation oncologist. The surgeon should be available if required. 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.

### Psychological Support

A clinical psychologist (psycho-oncologist) with special experience in seeing breast patient must be available at the Breast Unit.

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.

Regular support (advice, counseling, psychological help) is given by Breast Care Nurses in some countries and psychologically professionally trained persons with expertise in Breast Cancer in others.

### Follow-up of primary breast cancer

Follow up should be done within the Breast Unit by a multidisciplinary team made up of a surgeon, radiologist, radiation oncologist and medical oncologist. All necessary imaging investigation procedures should be done at the same visit.

The Unit must have a formal agreed protocol for follow up. If the follow up is not carried out by the Unit, the Unit should collect information yearly and include these data in the unit's database.

### Prosthesis

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

### Physiotherapy and Lymphoedema

There must be an identified Physiotherapist or a Breast Care Nurse for the treatment of lymphoedema and late sequelae.

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

### 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 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.

Table summarizing the mandatory and recommended requirements, divided by topic

Critical mass

<b>Item</b>	<b>Mandatory</b>	<b>Recommended</b>
<i>At least 150 newly diagnosed cases of primary breast cancer (all ages and stages) per year</i>	M	
<i>All primary treatment must be carried out under the direction of the Unit</i>	M	
<i>Operation must be in the Unit, all adjuvant therapies must be agreed at MDM</i>	M	

Clinical Director

<b>Item</b>	<b>Mandatory</b>	<b>Recommended</b>
<i>Unit must have an identified clinical Director</i>	M	

Protocols

<b>Item</b>	<b>Mandatory</b>	<b>Recommended</b>
<i>The Unit must have written protocols for diagnosis and management of cancer at all stages</i>	M	
<i>Protocols must be agreed by the core team members</i>	M	
<i>New protocols and protocols amendments must be discussed by the core team and formally recorded at audit meetings</i>	M	

## Audit

<b>Item</b>	<b>Mandatory</b>	<b>Recommended</b>
<i>Unit must have a database for audit purpose.</i>	M	
<i>Data that should be recorded in the database are: source of referral (screening programme, spontaneous screening, symptomatic), diagnosis, pathology, primary treatment and clinical outcomes</i>		R
<i>The Unit should also participate in an external bench marking activity.</i>		R
<i>The Unit team must hold at least one yearly audit meeting. A formal report of these meeting must be kept.</i>	M	
<i>Regarding performance, the Unit must achieve the minimum outcome for mandatory QI as indicated by Eusoma</i>	M	
<i>A data manager must be formally identified with responsibility for ensuring that all relevant data are collected, recorded and analyzed</i>	M	

## Multidisciplinary Case Management Meeting

<b>Item</b>	<b>Mandatory</b>	<b>Recommended</b>
<i>All members of the core team should attend MDMs</i>		R
<i>MDMs must be held at least weekly and must be minuted.</i>	M	

<i>The Unit must discuss at least 90% of cases</i>	M	
<i>It is recommended to include the discussion of patients that undergo diagnostic breast needle biopsy as well as cases where treatment planning is being considered</i>		R

Communication of the diagnosis, treatment plan and waiting time

<b>Item</b>	<b>Mandatory</b>	<b>Recommended</b>
<i>Patient should commence primary treatment within 4 weeks from the definitive diagnosis</i>		R
<i>The communication to the patient can be preliminary given by each specialist according to his/her competence, but following the appropriate MDM discussion to plan treatment, the results should be given to the patient by one clinician</i>		R
<i>It is recommended that a breast care nurse or a psychologically trained person be present to discuss fully with the patient the options for treatment and to give emotional support.</i>		R
<i>A suitable room with sufficient privacy should be available</i>		R

### Patient information

<b>Item</b>	<b>Mandatory</b>	<b>Recommended</b>
<i>Women must be offered clear oral and written information (leaflets) regarding diagnosis and treatment options</i>	M	
<i>It is recommended that these leaflets are personalized by the Breast Unit</i>		R
<i>The Breast Unit should also provide written information concerning local support groups and advocacy organizations.</i>		R
<i>Patients should be provided with the list of patients rights</i>		R

### Teaching

<b>Item</b>	<b>Mandatory</b>	<b>Recommended</b>
<i>Unit should provide teaching for junior staff or students on national or international level</i>		R
<i>Unit should organize one teaching course a year at local or national level</i>		R

### Research

<b>Item</b>	<b>Mandatory</b>	<b>Recommended</b>
<i>Units should record the number of patients entered in clinical trials and details of all other research</i>		R

Breast surgery and reconstructive surgery

<b>Item</b>	<b>Mandatory</b>	<b>Recommended</b>
<i>There must be at least 2 nominated specialist breast surgeons (including gynecologists performing breast surgery) specially trained in breast disease. Each of whom must carry out personally primary surgery on at least 50 newly diagnosed cancers per annum</i>	M	
<i>To be breast dedicated the surgeon has to spend at least 50% of his/her working time in breast disease</i>	M	
<i>The surgeon must participate in diagnostic, new patient and follow up clinics, and audit meeting</i>	M	
<i>The surgeon should attend MDMs</i>		R
<i>The surgeon should be able to undertake basic reconstruction, when required, and oncoplastic surgery</i>		R
<i>Training of breast surgeon should comply with what indicated in the Eusoma guidelines on health professionals</i>		R
<i>Sentinel node procedure must be available</i>	M	
<i>The Breast Unit must make arrangement with one or two nominated plastic surgeons with special interest in breast reconstructive and recontouring techniques</i>	M	



<i>The breast Unit should advise and where necessary treat benign disease.</i>		R
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### Breast Radiology

<b>Item</b>	<b>Mandatory</b>	<b>Recommended</b>
<i>There must be at least two nominated specialist breast radiologists</i>	M	
<i>Each of them must read a minimum of 1000 mammography cases per year</i>	M	
<i>Each radiologist participating in screening programme is recommended to read 5000 mammography cases per year</i>		R
<i>To be breast dedicated the radiologist must spend at least 30% of the working time in breast disease</i>	M	
<i>Radiologists must attend audit meeting, and at least one diagnostic clinic per week for symptomatic patients or screening assessment</i>	M	
<i>They should participate in MDMs</i>		R
<i>Training of breast radiologist should comply with what indicated in the Eusoma guidelines on health professionals</i>		R
<i>The Unit must be in possession of : mammography Unit, stereotactic biopsy attachment and/or</i>	M	

<i>dedicated prone biopsy table, ultrasound equipped with a small part probe <math>\geq 10\text{MHz}</math></i>		
<i>It is recommended that this equipment is not older than 10 years</i>		R
<i>Quality control of all equipment used for breast imaging must be routinely performed, according to the relevant national protocols and/or European Guidelines</i>	M	
<i>The unit must be able to perform: clinical examination, diagnostic mammography, ultrasound of the breast and axilla, core biopsy (free-hand, US-guided and X-ray guided) breast MRI (if not available within the hospital, the Unit must have in place an agreement with a local diagnostic service that provides breast MRI as recommended by Eusoma standards).</i>	M	
<i>The unit may also be able to perform: free hand and image guided FNAC, CB vacuum assisted, vacuum assisted mammotomy (VAM-image guided: ultrasound/x-ray/MRI guided)</i>		R
<i>It is recommended that a formal imaging risk classification is used (e.g. BIRADS™, European classification)</i>		R
<i>Breast Diagnostic radiographers must be responsible for performing</i>	M	

<i>mammograms</i>		
<i>The Unit must have at least 2 radiographers performing each 20mx per week</i>	M	
<i>Training of breast diagnostic radiographers should comply with what indicated in the Eusoma guidelines on health professionals</i>		R
<i>They should also attend refresher courses at least every 3 years.</i>		R
<i>Radiographers are recommended to follow the working practice recommendation defined in the European Guidelines (Ex: positioning, quality control)</i>		R
<i>Radiographers should participate in audit of their daily performance (retake analysis)</i>		R
<i>They should have a clear understanding of the requirements of technical quality control on day to day basis and should perform the daily quality control (sensitometry and phantom test for analogic mammographer and weekly phantom test for digital mammographer)</i>		R

### Breast Pathology

<i>The Unit must have a lead pathologist plus an additional one or two, depending on the Unit size.</i>	M	
<i>They should be responsible for</i>		R

<i>all breast pathology and cytology.</i>		
<i>To be breast dedicated a pathologist must spend approximately 25% of his/her working time in breast disease</i>	M	
<i>All specialist pathologists reporting breast cancer should see at least 50 primary breast cancer resections per year.<sup>(20)</sup></i>		R
<i>They should take part in available European, National and Regional quality assurance schemes</i>		R
<i>Pathologists must attend audit meetings.</i>	M	
<i>They should also participate in MDMs</i>		R
<i>Training for Breast Pathologists should comply with what indicated in the Eusoma guidelines on training for specialized Health Professionals.<sup>(19)</sup></i>		R
<i>The Service must be equipped with: processors, microtomes, staining machines and immunostainers.</i>	M	
<i>This equipment should not be older than 10 years and well maintained</i>		R
<i>With regard to workup of the specimen, items included in the report, nomenclature, special studies (Immunohistochemistry for diagnosis, Immunohistochemistry for ER +/-PR, access to her2 testing), the laboratory should refer to European Guidelines.<sup>(12)</sup></i>		R
<i>For core biopsy the Unit must use B-classification</i>	M	
<i>It is recommended to show</i>		R

<i>histology at MDM, preferably direct from slides.</i>		
<i>The laboratory should keep at least 10 years slides archived (2 years on site) and report for 25 years minimum, or following the relevant national protocols if available</i>		R
<i>Pathologist should be familiar with national and/or European performance quality standards and guidelines</i>		R

### Medical Oncology

<b>Item</b>	<b>Mandatory</b>	<b>Recommended</b>
<i>The unit must have a medical oncologist dedicated to breast cancer</i>	M	
<i>To be dedicated he/she has to spend around 40% of working time in breast cancer</i>	M	
<i>He/she must attend audit meeting, advanced breast cancer clinics and other clinics (loco-regional, recurrent clinic)</i>	M	
<i>They should also participate in MDMs</i>		R
<i>Supervision of systemic therapies and/or decision making process for adjuvant and neo-adjuvant treatments should be in accordance with local/institutional rules and supervised by the designated medical oncologist</i>		R
<i>The Unit should aim to enroll at least 10% of all patient in clinical trials</i>		R

<i>Training of breast medical oncologist should comply with what indicated in the Eusoma guidelines on health professionals</i>		R
<i>In case patients decide to have chemotherapy treatment in another hospital, the decision regarding the type of treatment must be decided at MDT of the unit.</i>	M	
<i>If Medical Oncology Unit is not available within the hospital, the Breast Unit must have an agreement with a medical oncology unit and the medical oncologist should attend MDMs at the Breast Unit.</i>	M	
<i>Outcome information on all patients treated with a systemic therapy should be collected even if patients are treated elsewhere</i>		R

### Radiation Oncology

<b>Item</b>	<b>Mandatory</b>	<b>Recommended</b>
<i>The Unit must have a nominated radiation oncologist dedicated to breast cancer</i>	M	
<i>He/she must attend audit meeting, advanced breast cancer clinics and loco regional, recurrent clinics</i>	M	
<i>He/she should attend MDMs</i>		R
<i>To be breast dedicated He/she has to spend at least 30% of their clinical time in breast disease</i>	M	

<i>Training of breast radiation oncologist should comply with what indicated in the Eusoma guidelines on health professionals</i>		R
<i>The minimum equipment must include at least two megavoltage units, a simulator and a computerized 3D planning system</i>	M	
<i>The department must have a radiotherapeutic quality control programme for breast cases</i>	M	
<i>The Unit must also have a quality control programme and perform the verification of the linear accelerator output</i>	M	
<i>The Unit must also take measure to protect lung and heart: preferably 3D dose volume histograms</i>	M	
<i>Experience in special techniques such as IMRT, partial breast irradiation, gating, 3D brachytherapy is recommended</i>		R
<i>If the radiotherapy Unit is not available within the hospital, the Unit must have an agreement with a radiotherapy service .</i>	M	
<i>The radiation oncologist should attend MDMs at the breast unit</i>		R

### Breast Care Nursing

<b>Item</b>	<b>Mandatory</b>	<b>Recommended</b>
<i>At least two breast care nurses are needed per</i>	M	

<i>breast Unit</i>		
<i>Training of breast care nurses should comply with what indicated in the Eusoma guidelines on health professionals and EONS core curricula for breast care nurses</i>		R
<i>To be breast dedicated he/she has to spend at least 30% of the time to breast cancer care</i>	M	
<i>Breast care nurses should attend MDMs</i>		R
<i>They must be available to counsel and offer practical advice and emotional support to newly diagnoses patients at the time the diagnosis is given, so as to further explain treatment plans. They must be present to support women when diagnosis that the disease has become advanced is given</i>	M	
<i>They should also be available on demand from patients in the primary breast cancer follow up clinics and advanced clinics</i>		R

Other services:

Clinics

<b>Item</b>	<b>Mandatory</b>	<b>Recommended</b>
<i>All consultation for breast disease must be done in dedicated clinics</i>	M	



Clinical genetics clinic

<b>Item</b>	<b>Mandatory</b>	<b>Recommended</b>
<i>The Unit must have a clinical geneticist with a special interest in breast cancer</i>	M	
<i>Unit that are not running a genetic service must have in place an agreement with an hospital where the service is available</i>	M	
<i>Advice is best given in a multidisciplinary clinic, the specialists involved are a clinical geneticist and from the team a breast surgeon, gynecologist, a breast radiologist and a clinical psychologist</i>		R
<i>The patient data from these clinics should be formally recorded in an appropriate database and this team should be actively involved in research</i>		R
<i>Gene testing must be available when required</i>	M	
<i>A molecular geneticist should be accessible for consultation by the specialists of the clinic</i>		R
<i>Risk assessment counseling and DNA testing for BRCA mutations in selected high risk group should be offered, in accordance with the Unit protocols</i>		R
<i>The clinical genetic service should offer: Mutation analysis Genetic testing should include complete sequencing of coding regions, either directly of</i>		R

<i>after a screening method. Specific techniques to detect duplications or deletions of one or more exons may be indicated.<sup>(22)</sup></i>		
<i>Diagnostic Surveillance Unit should have written protocols where diagnostic surveillance is specially considered for high risk women including screening MRI according to the risk level</i>		R
<i>Other intervention The unit should have a written protocol for prophylactic operations and chemoprevention.</i>		R
<i>Psychological support should be given to patients when necessary to adjust them to the situation, to help them to cope with stress and to support their individual decision-making<sup>(23)</sup></i>		R

New patients clinic

<b>Item</b>	<b>Mandatory</b>	<b>Recommended</b>
<i>At least one clinic per week for newly referred symptomatic women must be held</i>	M	
<i>These clinics must be staffed by a surgeon or a radiologist from the breast care team</i>	M	
<i>Multidisciplinary working should allow all standard investigations for triple assessment (clinical examination and all appropriate imaging and</i>		R

<i>tissue diagnostic procedure) to be completed at one visit.</i>		
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Advanced breast cancer clinic

<b>Item</b>	<b>Mandatory</b>	<b>Recommended</b>
<i>Advanced breast cancer patients must be seen within the Breast Unit</i>	M	
<i>These clinics must be separate from the general oncology clinics and attended by the medical oncologist and radiation oncologist</i>	M	
<i>The surgeon should be available if required</i>		R
<i>Patients with distant metastases locally advanced primary breast cancer and local /regional recurrence must be managed in this clinic according to protocols agreed by the multidisciplinary team</i>	M	

Psychological support

<b>Item</b>	<b>Mandatory</b>	<b>Recommended</b>
<i>Clinical psychologist (psycho-oncologist) with special experience in seeing breast cancer patient must be available at the breast Unit</i>	M	
<i>If the patient is experiencing psychological morbidity that can not be dealt by unit member, the patient should be referred to a psychiatrist</i>		R

### Follow up of primary breast cancer

<b>Item</b>	<b>Mandatory</b>	<b>Recommended</b>
<i>Follow up should be done within the Breast Unit, by multidisciplinary team made up by the surgeon, radiologist, radiation oncologist, medical oncologist. All necessary imaging investigation procedures should be done at the same visit</i>		R
<i>The Unit must have a formal agreed protocol on follow up</i>	M	
<i>If the follow up is not carried out by the Unit, the Unit should collect information yearly and include these data in the unit database</i>		R

### Prosthesis

<b>Item</b>	<b>Mandatory</b>	<b>Recommended</b>
<i>The provision for a prosthesis fitting service should be within the unit</i>		R

### Physiotherapy and lymphoedema

<b>Item</b>	<b>Mandatory</b>	<b>Recommended</b>
<i>An identified physiotherapist or breast care nurse must be available for the treatment of lymphoedema and late sequelae</i>	M	
<i>Physiotherapy must be available for the post-operative recovery period to ensure good shoulder mobility, etc</i>	M	

Palliative Care

<b>Item</b>	<b>Mandatory</b>	<b>Recommended</b>
<i>A specialist palliative care service must be available for the referral of patients with advanced breast cancer</i>	M	
<i>A close relationship must be established between the members of the breast Unit and the palliative care service</i>	M	

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### **Revision Committee:**

This is a revised version of the up-dated version published in the 4<sup>th</sup> Edition of the European Guidelines for Breast Cancer Screening and Diagnosis

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