

# A Short Guide to the European Guidelines for quality assurance in breast cancer screening and diagnosis



# Mission

**EUROPA DONNA – The European Breast Cancer Coalition, is an independent non-profit organisation whose members are affiliated groups from countries throughout Europe.**

The Coalition works to raise awareness of breast cancer and to mobilise the support of European women in pressing for improved breast cancer education, appropriate screening, optimal treatment and increased funding for research. EUROPA DONNA represents the interests of European women regarding breast cancer to local and national authorities as well as to institutions of the European Union.

## **The European Guidelines for Quality Assurance in Breast Cancer Screening and Diagnosis**

are key to enabling EUROPA DONNA to achieve its mission for the benefit of all women across Europe. The guidelines set the standards for mammography screening, diagnosis and requirements for specialist breast units. They are a fundamental tool for EUROPA DONNA advocates in the Coalition's member countries, including all EU Member States.

EUROPA DONNA lobbies relentlessly for the implementation of the guidelines in all countries within and beyond the EU, so that women will have high-quality breast care wherever they live.



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European Commission

*The chapter numbers and titles in this guide correspond to those in the current, 4th Edition of the EU guidelines. To obtain the 4th Edition, see page 33.*

# Why **have A Short Guide to the EU Guidelines**

→ **The European guidelines must be implemented across Europe so that mammography screening programmes, diagnostic procedures, treatment and aftercare for breast cancer are of the highest quality.** The European Commission has published guidelines to establish recommendations for high-quality screening, diagnosis and the setting up of specialist breast units in order to achieve the best medical practice and care possible. EUROPA DONNA has created this Guide to the EU Guidelines to assist in the achievement of this standard. It highlights the key points of each chapter in the guidelines following the structure of the guidelines document. Readers are encouraged to refer to the full guidelines for their complete recommendations.

→ **Women, advocates, politicians and policy makers need to know what high-quality mammography screening and breast care services to expect, demand and implement.** EUROPA DONNA has created this concise, easy-to-distribute description of the EU Guidelines to emphasise the scope and the main points in the 400-page document. It is hoped that in this way the many important recommendations and standards in the EU Guidelines will become more readily accessible to any interested person. This, in turn, should help women, advocates and politicians work together to ensure that the best breast cancer services are available to women wherever they live.

→ **The guidelines were created with input from top European cancer organisations and are EUROPA DONNA's reference document for benchmarking and best practice.** Over 200 professionals and client and patient advocates from 23 countries contributed to the fourth edition of the guidelines. Its production was co-ordinated by the European Reference Organisation for Quality Assured Breast Screening and Diagnostic Services (EUREF) project in the European Breast Cancer Network (EBCN, now the ECN) with input from the United Kingdom National Guidelines and experts of the European Society of Mastology (EUSOMA), as well as EUROPA DONNA advocates.

→ **Breast cancer affects more women than any other cancer.** One in ten European women will develop breast cancer in her lifetime. As the population ages, more and more women will be affected by this disease. It accounts for over 26% of all cancers and over 17% of all cancer deaths in women.

→ **Mammography screening helps to detect cancer early.** It can detect cancers three to four years before a woman would notice the symptoms herself and increases her chances of earlier, less invasive treatment. Studies have shown that breast cancer mortality is reduced by about 35% in women 50-69 years of age who accept an invitation to breast cancer screening.

*To obtain the current, 4th Edition of the European Guidelines and other relevant publications, see page 33.*

# Why the EU Guidelines are so important

The **quality of breast cancer** care that European women receive today differs from country to country and from region to region.

The 2015 and 2010 **Written Declarations on the Fight Against Breast Cancer in the European Union**, the 2006 **European Parliament Resolution on Breast Cancer in the Enlarged European Union**, and the first Resolution of 2003, call for every woman across Europe to have access to **equal, high-quality breast cancer care**, in compliance with the European guidelines. The aim is to **reduce mortality from breast cancer** across the EU and to **reduce the disparity in survival rates between countries**.

The European Parliament has judged the most effective means of reducing disparities in care and mortality to be through **population-based mammography screening programmes** and the setting up of **specialist breast units**, as well as through training and auditing to assure quality standards.

The **effectiveness of mammography screening** depends upon the good condition of the equipment, the skill of the person operating it and the person interpreting the results. Effective screening programmes also reduce possible negative effects of screening, such as anxiety.

Mammography screening should be offered **every two years to all women aged 50-69** as part of the public health system. This is in keeping with both International Agency for Research on Cancer (IARC) recommendations and the European Council Recommendation on Cancer Screening.

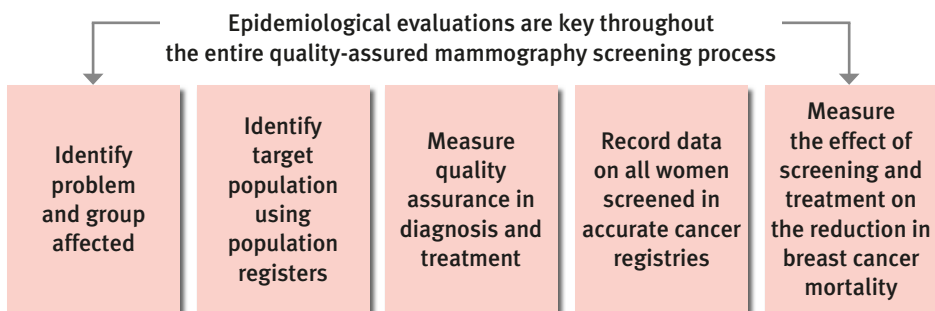
The European guidelines set **clear quality standards for all aspects of screening and diagnosis** and have specific chapters dedicated to each discipline involved. Whilst they focus on screening mammography in women without symptoms, recommendations are also provided for women with symptoms of breast cancer.

**Adherence to high-quality standards across all aspects of screening programmes** will improve care for women participating in the programmes and for all women requiring breast care.

## Chapter 1

## Epidemiology

- **Epidemiological evaluations** are needed in order to set up a mammography screening programme, to monitor the various stages of the programme, and to verify its success.



- **Accessible, accurate registers**, such as census data or population registers, are needed to identify the women to be invited for screening and they must be kept up to date.
- **Information campaigns** should be held to encourage women to participate in screening.
- Methods of collecting and reporting mammography screening information need to be unified, using the **terminology, definitions and classifications** recommended in the EU guidelines.
- **Continuous follow-up** of the women targeted for screening is required to monitor the effectiveness of the screening programme. This should be provided in co-operation with **population-based cancer registries**.

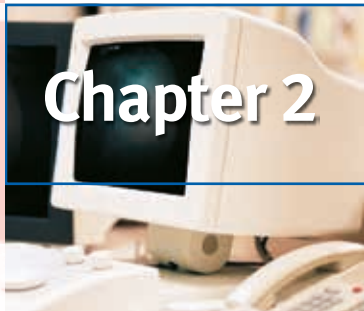
- Cancer registry data are needed in order to predict whether or not a programme will be effective in lowering breast cancer mortality, because mortality reduction in the population takes many years before it can be measured accurately. An early indicator of effectiveness is the number of **advanced tumours detected among screened women**, which should decrease sooner than mortality.
- Cancers detected in the time between routine screenings (**interval cancers**), along with their tumour size and stage, are to be **recorded separately** from those detected during screening.
- **The success of the programme** should be judged not only by the programme's effect on public health, but also by its organisation, implementation, execution and acceptability, as well as the number of women who participate, the number who are recalled for further assessment, how many are assessed, and the cost-effectiveness of the programme.

#### Epidemiological requirements for an effective screening programme

- ✓ Available and accurate epidemiological data for the population being screened
- ✓ Accurate population registries and demographic data
- ✓ Available and accessible high-quality breast cancer diagnosis and treatment services
- ✓ Promotion to encourage participation
- ✓ Follow-up of screened women
- ✓ Co-operation between screening programmes and cancer registries

# Chapter 2

## Physical and technical aspects of mammography



The **physical and technical guidelines** set the quality control standards for mammography equipment and its proper functioning.

*Regular quality control is conducted to guarantee:*

- ✓ The provision of images with the best possible diagnostic information, to detect even smaller tumours or irregularities
- ✓ Stable image quality that is consistent with that obtained in other mammography screening centres
- ✓ The dose of radiation a woman receives is as low as reasonably achievable

### Chapter 2a: Screen-film mammography

*This is the standard mammography technology in which images are processed on film and viewed on light boxes.*

- **All mammography equipment**, such as X-ray equipment, image receptors, film processors and the quality control test equipment itself must undergo **strict quality control testing** before it is used and **optimal levels must be maintained** once it is in use.
- Some regular quality control measurements can be performed by the local staff, while others must be conducted by **specifically trained medical physicists**. All must follow a **written protocol** meeting the requirements of the quality assurance programme.



### System components and parameters to be monitored

- ✓ X-ray generator and exposure control system
- ✓ Bucky (film cassette holder) and the image receptor
- ✓ Film processing (for screen film systems)
- ✓ Image processing (for digital systems)
- ✓ System properties (including radiation dose)
- ✓ Monitors and printers (for digital systems)
- ✓ Viewing conditions

## Chapter 2b: Digital mammography

*In this newer technology, the image is stored in a computer where it can be enhanced, magnified, or manipulated for further evaluation. The image is viewed on a computer monitor and printed.*

- **The quality control evaluation must be specific to digital mammography** systems, which differ from screen film systems.
- Digital systems should incorporate an **automatic exposure control**.
- Digital images must be viewed in **lower light conditions** than screen film mammography, due to the lower light intensity of the viewing monitor.

*Given the limited experience with digital mammography to date, updates to the digital mammography guidelines will be available on the EUREF website [www.euref.org](http://www.euref.org)*

Chapter 3

# Radiography

- **Radiographers** are responsible for producing the **high-quality mammograms** necessary to detect breast irregularities, and for processing and assessing the mammograms. Their duties include implementing and conducting **quality control procedures** for equipment monitoring and overseeing maintenance and repairs.
- **Radiographers** are usually the only health care professionals a woman meets in a screening programme and should therefore establish a **good rapport** with the woman undergoing screening in order to ensure a **satisfactory experience**.

## *Before starting, the radiographer should:*

- ✓ Ask the woman about her previous mammography experience and any current or past breast information
- ✓ Explain the examination procedure and the need to take mammograms from two views, which helps to detect irregularities and to limit recalls for reassessment
- ✓ Explain the reason for compressing the breast. Compression creates better images, reduces blurring caused by movement, spreads out the breast tissue, and it reduces the dose of radiation
- ✓ Be up-to-date in issues for which women may require more information, such as silicone implants or hormone replacement therapy
- ✓ Answer any questions the woman may have and explain the process and timing for receiving results

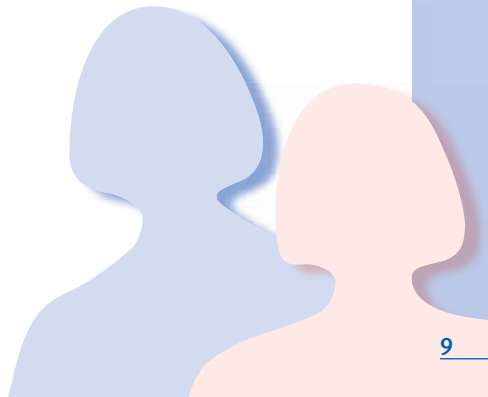


- **Radiographers** in screening programmes must work a **minimum of two days per week** in order to maintain their mammography skills. Those participating in symptomatic breast services should perform at least **20 mammographic examinations per week**.
- **Radiographers** must have the skills to **optimally position the breast** for mammography. Incorrect positioning is the most common problem in mammogram evaluation.

### Common criteria for quality assessment of the breast image

- ✓ Correct positioning of automatic exposure device
- ✓ Appropriate compression
- ✓ Absence of skin folds, overlying objects such as shoulders, movement, other objects such as dust on the screen
- ✓ Correct identifications
- ✓ Correct exposure
- ✓ Correct film development technique
- ✓ Symmetrical images

- More than **97%** of the women screened should have an acceptable examination and be **satisfied with their screening visit**.
- **Less than 3%** of the women should have a **repeat examination**. This should be audited.
- **Radiographers** should undergo three days to one week of **academic mammography training** and two to six weeks of **clinical training**.
- **Radiographers** should participate in **multidisciplinary team meetings**.



# Chapter 4

# Radiology

- Radiologists take **prime responsibility for the mammogram image quality and diagnostic interpretation**. The lead radiologist of the screening programme should ideally act as the clinical director of the programme.

## *Professional requirements of the radiologist*

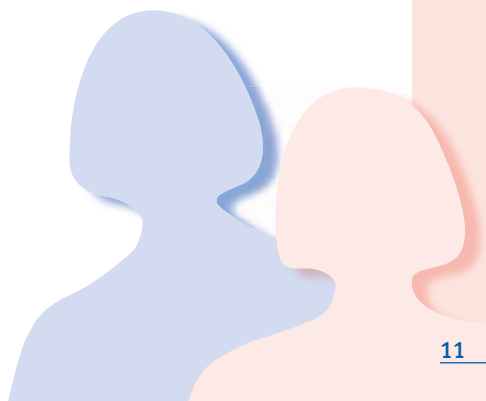
- ✓ Medical qualification
- ✓ Specific training in symptomatic mammography and screening mammography
- ✓ Participation in continuing medical education programme and external quality assessment scheme
- ✓ Minimum of 5,000 mammograms read per year in centralised screening programmes

- **Two different radiologists** should read each screening mammogram independently, since this improves the likelihood of a correct reading by 5–15%. **Double reading** is recommended in centralised screening programmes and is mandatory in decentralised programmes, where the second reading should be carried out at a centralised level by an experienced radiologist reading at least 5,000 mammograms per year.
- **Radiologists must refuse to accept unsatisfactory mammograms** and demand that they be repeated. All repeat mammograms should be recorded.
- **The radiologist** should lead the assessment process when women are recalled for examination based on an abnormal finding at screening. This process should involve a **triple assessment** of clinical examination, further imaging and cell/tissue sampling.

- In the case of impalpable irregularities identified on screening, **the radiologist** is responsible for the **localisation procedure** prior to the surgical removal of the tissue for either diagnostic or treatment purposes. **Lesions must be satisfactorily removed** in over 90% of cases at the first operation.
- Radiologists must **review cases of interval cancers** (cancers diagnosed between screening rounds) for educational purposes.
- Radiologists must work closely with other colleagues as part of a **multidisciplinary team**.

*Practical radiological requirements for a screening programme:*

- ✓ Double reading of films in decentralised programmes
- ✓ Participation in internal and external audits
- ✓ Assessment of abnormalities detected through screening
- ✓ Review of cases of interval cancers





# Chapter 5

## Multidisciplinary aspects

**Modern diagnosis of breast disease involves a multidisciplinary team** of trained, experienced professionals using specialised equipment and diagnostic techniques.

- **The key professional personnel** involved in diagnosing breast cancer are the surgeon or clinician, the radiologist, radiographer, pathologist, nurse counsellor and physicist. The clinician, whether a general practitioner, a surgeon or radiologist, holds the prime responsibility in symptomatic cases.
- All women with symptoms of breast cancer should be referred to a **specialist breast unit**, the requirements for which are provided in Chapter 9 of the guidelines.
- Every woman's case and results should be discussed in a **multidisciplinary meeting** before and after surgery.
- Chapter 5 outlines the requirements for **diagnostic breast imaging units**, offering only mammography or ultrasound, and **diagnostic breast assessment units**, providing additional testing to women with suspicious imaging findings or symptoms.

### Diagnostic breast imaging unit requirements\*

- ✓ Perform at least 1,000 mammograms per year
- ✓ Possess specific equipment for diagnostic mammography and ultrasound and adequate viewing conditions
- ✓ Adhere to the physico-technical requirements in Chapter 2 of the guidelines
- ✓ The professional performing the mammography must have a minimum of 40 hours of specific radiographic training for mammography and take part in regular quality assessment schemes and refresher courses
- ✓ Employ a trained radiologist with at least 60 hours of specific training and reading at least 500 mammograms per year
- ✓ Have a clear procedure for referring women requiring further testing to a breast assessment unit or a specialist breast unit
- ✓ Keep record of results and the number of women referred for assessment
- ✓ Provide feedback on results of further assessment to the unit radiologist



### Diagnostic breast assessment unit requirements\*

- ✓ Perform at least 2,000 mammograms per year
- ✓ Have the capability to perform radiographic procedures, physical examinations, ultrasound, cytological examination and core biopsy sampling
- ✓ Employ a trained radiologist with experience of reading at least 1,000 mammograms per year
- ✓ Have pathology support services
- ✓ Take part in regular multidisciplinary review meetings
- ✓ Monitor data and results
- ✓ Keep formal records of the assessment process and outcomes

\*As also stipulated in Chapter 11 Certification protocol for breast screening and diagnostic services.

- **Delays** at any stage of the diagnostic process **must be avoided** as they can cause anxiety.
- 90% of women with signs or symptoms of breast cancer are to be offered an **appointment within two weeks of referral**.
- 95% of women should be **fully assessed in three appointments or less**.
- Women should be told about a likely breast cancer diagnosis in person **in the presence of a nurse counsellor**, not by post or over the telephone.

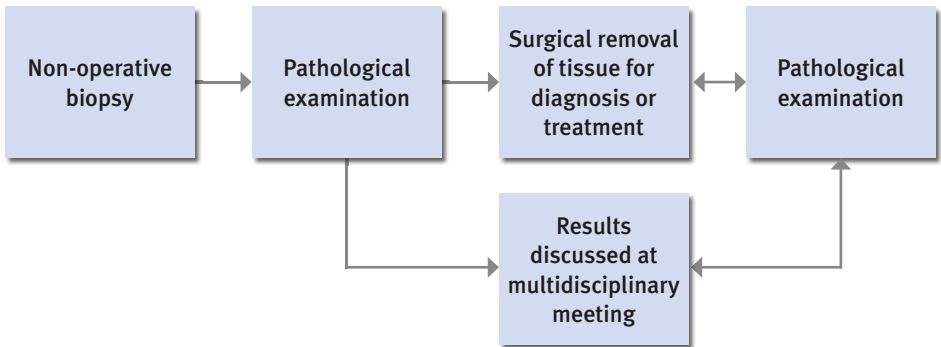
### Time (in working days) between the various stages of assessment and diagnosis

	Targets
Time from mammography to result	< 5 working days
Time from result of imaging to assessment	< 5 working days
Time from assessment to issuing of results	< 5 working days
Time from decision to operate and date for surgery	< 15 working days (ideally <10)

# Chapter 6

# Pathology

- **Pathologists** analyse the breast tissue obtained through **non-surgical or surgical procedures** and make a diagnosis based on their findings.
- **The pathological analysis** should form part of the **triple assessment** (clinical examination, imaging and cytological/histological sampling) used to discuss diagnosis at a multidisciplinary meeting and to help determine therapy.
- **Accurate pathological diagnoses** and the provision of information about tumour cells that is relevant to prognosis are necessary to ensure that a woman receives **appropriate treatment** and that a screening programme is properly monitored and evaluated.



## Chapter 6a: Non-operative diagnostic techniques

- **Screening programmes** should offer **high-quality non-operative diagnostic procedures**, allowing rapid referral for treatment. Such procedures also help to provide a definitive diagnosis for benign conditions so that surgery can be avoided. Screening programmes may be judged by the quality of their non-operative diagnostic service.



- **Three non-operative methods** exist for taking a sample of suspicious tissue and each has specific indications: fine needle aspiration cytology (FNAC), needle core biopsy (NCB) and vacuum-assisted needle core (VANC) biopsy.
- **Only experienced professionals** must be involved in or supervise sample taking or cytological/histological diagnosis.
- **Pathologists should record all data** using a standard reporting form, including the radiological appearance of the abnormality, the localisation technique, specimen type, the presence or absence of calcification. Their diagnostic opinion should be stated using one of five main categories ranging from B1 (normal tissue) to B5 (malignant).

## Chapter 6b: Open biopsy and resection specimens

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- **Surgical removal of tissue** for pathological examination can be performed for diagnostic or treatment purposes, although definitive non-operative diagnosis of benign conditions can usually avoid surgery.
- **Pathologists must have knowledge of the surgical technique used** and consider it when choosing the pathological technique for analysing the tissue specimen. The pathologist should be informed of any variations from surgical protocol in the request form.
- Due to the increasing trend to obtain fresh-frozen samples for biological research, special precautions should be taken to assure that **the whole unfixed specimen is sent immediately to the pathology laboratory**, where the pathologist should ink the entire surface of the specimen in order to determine the excision lines.
- **Pathologists should examine all lymph nodes** they receive and include the total number and those with metastases in their report. The pathologist and the surgeon should agree upon protocols for the examination and handling of samples from sentinel node biopsy.
- **Pathologists should record all findings** on standard histopathological report forms and should include prognostic data such as **tumour size, disease extent, grade, type, vascular invasion, marginal status and receptor status**.

# Chapter 7

# Surgery

- As a member of the multidisciplinary team, the surgeon plays a role in both the **diagnosis and the treatment** of breast cancer. Surgeons must be **specialty trained** in breast surgery and have undergone **courses in communication and counselling**. They should always see and examine a woman before operating on her.
- The majority of women (more than 70%) should not have to have an operation to determine their diagnosis; the use of **non-surgical diagnostic techniques** should help limit the operations performed on women who in fact do not have cancer.
- In cases of impalpable lesions such as microcalcifications, **radiography of the specimen** should be performed during surgery to ensure that the entire lesion has been removed. Surgeons should ensure that women are aware that **breast-conserving surgery** to remove just the affected area is the treatment of choice for most small screen-detected cancers, and should be provided in 70–80% of cases.
- Surgeons should offer a **mastectomy** to women who prefer this procedure and to those who are not good candidates for **breast-conserving surgery** due to the size of the tumour (> 4 cm), or high risk of recurrence, for example. They should offer the women the **choice of breast reconstruction** at the time of surgery or afterward.
- Women with larger tumours should be offered chemotherapy before surgery (**neoadjuvant treatment**) to try to reduce the size of the tumour before operating.
- **Surgeons should leave clear margins** around the removed tumour tissue and the pathologist should document the margins.
- All surgeons performing the **sentinel node procedure** to identify the presence of disease in the axillary lymph nodes should be specifically trained in the procedure and be evaluated.
- All women who are treated for breast cancer should undergo **follow-up** at least annually to measure outcome and recurrence.

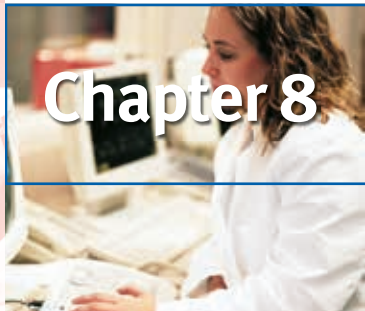
## Chapter 7a: Surgical management of mammographically detected lesions

- ✓ Surgeons should be fully involved in the assessment of screen-detected cancers and no more than one week should elapse between a woman's first recall appointment and her assessment for surgery
- ✓ In 90% of cases with a clear malignant diagnosis, the woman should only have to undergo one operation to remove the tumour. The surgeon must make sure that the woman is aware of all her treatment options
- ✓ In 90% of cases, women should not have to wait more than two weeks for surgery
- ✓ Each screening centre must nominate a surgeon responsible for recording audit information on screening, treatment and outcome, in order to generate reports on these issues and provide annual results

## Chapter 7b: Locoregional treatment of invasive breast cancer

- ✓ Every woman with invasive cancer considered suitable for breast-conserving surgery must be informed of this option.
- ✓ Women undergoing breast-conserving surgery or mastectomy should have a consultation with a radiation oncologist, since radiation improves breast tumour control
- ✓ The surgeon or plastic reconstructive surgeon should inform women having a mastectomy about the possibilities of breast reconstruction
- ✓ Over 80% of patients with locally advanced breast cancer should have combined therapy of upfront chemotherapy, cytoreductive surgery and radiation therapy
- ✓ The use of adjuvant radiotherapy should be discussed with all women after complete removal of ductal carcinoma *in situ*





## Chapter 8

# Data collection and monitoring

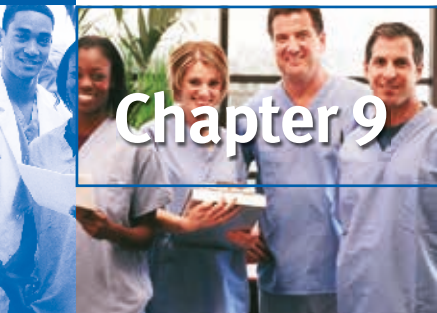
- **All aspects of breast cancer detection** and care – from screening, to assessment, diagnosis and treatment – should be monitored.
- **Multidisciplinary breast units** should be responsible for pursuing internal and external audit of their services.
- All screening or diagnostic units should have a **staff member responsible for co-ordination of data collection and reporting**.
- **Universally recognised classification and coding** should be used to facilitate comparisons.
- All data should be provided on **standard reporting forms** used in everyday practice.
- All data reporting should include **quality assurance criteria** in order to avoid duplication of effort. All measures of quality should be reproducible and clearly specified, and monitoring costs should be acceptable.
- All data collection and monitoring results should be **accessible to patients and advocacy organisations**.
- **Computerised audit systems** that calculate the majority of the quality indicators can be used. The European Screening Evaluation Database (SEED) and the Audit system of Quality of breast cancer diagnosis and Treatment (QT) exist for data monitoring in screening programmes.

## *Advantages of audit systems:*

- ✓ Unification of data reporting and terminology
- ✓ Consistent calculations methods used for outcome measures
- ✓ Easy production of standard reports within the screening or breast unit

## *Requirements of audit systems:*

- ✓ Periodic updating is necessary once the quality objectives, recorded items and clinical classifications are defined
- ✓ Linking of systems to professional and scientific organisations is required for system approval
- ✓ Systems must be easy to use



## Chapter 9

# The requirements of a specialist breast unit

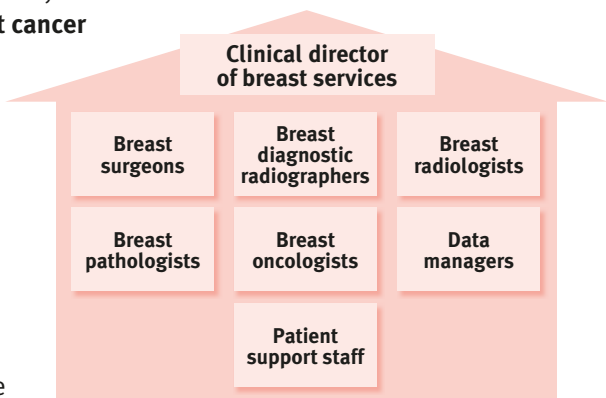
Women must be offered quality care for all stages of breast disease, from the earliest stages detected in screening to the most advanced cancer, within one **specialist breast unit**, where the care and follow-up are provided by the same **core team of specialists**.

### Minimum quotas ensure the expertise of the unit and its staff

- ✓ There must be one specialist breast unit for every 250,000 to 300,000 population
- ✓ The unit must be large enough to have a minimum of 150 newly diagnosed cases of breast cancer per year
- ✓ Surgeons in the breast unit must perform surgery in a minimum of 50 new breast cancer cases per year and attend at least one diagnostic clinic per week
- ✓ Radiologists must read a minimum of 1,000 mammograms per year, or 5,000 for those working within screening programmes. There must be at least two qualified radiologists in each unit

### Every unit must have a multidisciplinary core team

- The unit must have a **clinical director** of breast services.
- All members of the multidisciplinary team must have **special training in breast cancer** obtained by spending one year in a unit recognised for training.
- All members of the multidisciplinary team must attend a **multidisciplinary meeting**, held a minimum of once per week, to discuss diagnosis, pathological findings following surgery and to evaluate treatment options.



Section 9.5.2 The breast unit core team.



## Facilities and services

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- The unit must have the **imaging equipment** necessary to ensure complete and adequate breast diagnosis.
- **Radiotherapy and cytotoxic chemotherapy** may be given within the breast unit or in a separate clinic or hospital. However, the treatment a woman receives must be **supervised by the breast unit** and all treatment decisions made by its multidisciplinary team.
- An **Advanced Breast Cancer Clinic** must be held once every two weeks at the breast unit, involving the clinical or medical oncologist, and the surgeon must be available for consultation.
- A breast unit should hold **outreach clinics** in the smaller hospitals if these are at a distance from the breast unit. Outreach programmes are preferable to small breast units in low population areas as they ensure that women receive expert breast care. Outreach clinics should be held at least once a month.

## Special services

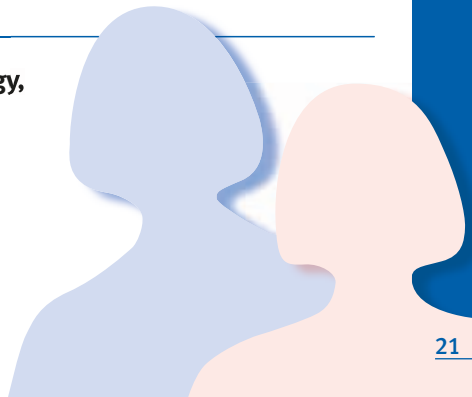
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- Women should receive **practical advice, support and counselling** from **specialist breast care nurses** or a core team member with professional psychological training. All units should have at least two staff members serving this function.
- Other professionals who are not mandatory core personnel should offer services associated with the unit: **psychiatrists** for extra psychological support, **plastic surgeons** for breast reconstruction, **physiotherapists** to treat lymphoedema, **clinical geneticists** to assess risk, a **palliative care service**, and there should be a **prosthesis fitting service** within the unit.

## Quality assurance

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- Units must **record data on diagnosis, pathology, primary treatment and clinical outcomes**, and these data must be available for audit.
- **Performance and audit figures** must be produced yearly and they must be compared to defined quality objectives and outcome measures.





# Chapter 10 Training

- **All medical staff** in a breast cancer screening programme must undergo specific training in the **academic and clinical aspects of screening**, such as epidemiology, screening philosophy, screening terminology, evaluation and current screening practices.
- Staff should be trained at an **approved training centre** before entering any programme.
- As multidisciplinary services have been proven to be the most effective, specialists should be offered training in both **unidisciplinary and multidisciplinary** settings where they also learn the importance of **communicating with their colleagues** in other disciplines.
- Since technology, procedures and protocols change, specialists should take **continuing education and refresher courses** and acquire certification for them.
- Staff participating in training courses should receive a **certificate of attendance** based on their skills and performance.
- Breast units and clinics should **keep records of training activities** for review as an indicator of the quality of the unit.



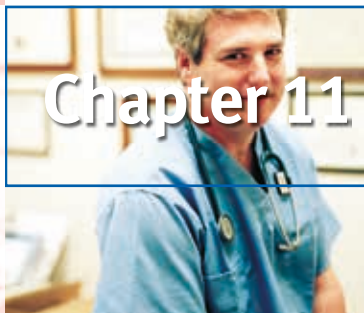


### Some essential topics for theoretical training courses:

- ✓ Screening philosophy
- ✓ Breast cancer screening terminology
- ✓ Setting up a breast cancer screening programme
- ✓ Breast imaging: mammography, ultrasound, MRI, localisation techniques
- ✓ Radiological-pathological correlation of benign and malignant lesions
- ✓ Classification and management of invasive and *in situ* breast cancer
- ✓ Classification and management of benign breast disease
- ✓ Management of screen-detected breast disease
- ✓ Breast reconstruction
- ✓ Radiotherapy for breast cancer
- ✓ Chemotherapy and hormonal therapy for preoperative and adjuvant treatment of breast cancer
- ✓ Psychological evaluation, communication and counselling
- ✓ Hereditary breast cancer and genetic counselling
- ✓ Epidemiology and principles of breast cancer screening
- ✓ Multidisciplinary meeting for pre- and post-surgical management of cases
- ✓ Principles and practice for audit procedures
- ✓ Clinical trials and statistics

### *Specific training sections in Chapter 10:*

- 10.3 Epidemiologist
- 10.4 Physicist
- 10.5 Breast radiographer
- 10.6 Breast radiologist
- 10.7 Breast pathologist
- 10.8 Breast surgeon
- 10.9 Breast care nurse
- 10.10 Medical oncologist/radiotherapist



## Chapter 11

# Certification protocol for breast screening and diagnostic services

- **The certification protocol** in the EU guidelines establishes the **minimum requirements for certification of diagnostic and screening units**. This topic is to be further addressed in the next edition of the EU guidelines, and a European Commission-approved certifying body is to be created.
- Certification provides documentation signifying that the **standards set in the EU guidelines** for breast screening and diagnosis have been achieved. Certification can be withdrawn if standards are not maintained.
- Certification will be **voluntary** until such a time that the European Commission or other authorities deem it mandatory.
- **Re-certification** should be obtained every 5 years to ensure maintenance of quality services.
- Certification may be granted based on **specialised site visits**: the advisory visit within the first year of a screening programme to assess its adherence to the EU guidelines; and the pre-certification visit during the second screening round to advise of shortcomings and which could prevent successful certification and offer appropriate advice and support to facilitate requisite improvements.
- As breast diagnostic imaging services and breast screening programmes – with their wider organisational and epidemiological support – have different requirements and facilities, certification has been divided into two categories: **Diagnostic Breast Imaging Certificates**, for diagnostic units, and **Breast Screening Certificates**, for organised population-based screening programmes.

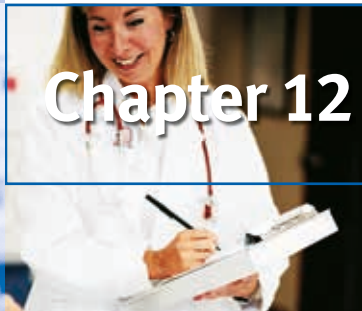
**Basic criteria  
for the  
certification of  
the diagnostic  
breast imaging  
units and  
screening units:**

Type of unit	Mammograms per year	Population served	Radiographer training in mammography	Radiologist training in mammography	Radiologist mammograms read per year
Diagnostic breast imaging unit	≥ 1,000	—	≥ 40 hours	≥ 60 hours	≥ 500
Diagnostic breast assessment unit	≥ 2,000	—	≥ 40 hours	≥ 60 hours	≥ 1,000
Loco-regional screening programme	≥ 5,000	≥ 20,000 women	≥ 40 hours	≥ 60 hours	≥ 5,000
European reference centre for breast screening	≥ 10,000	≥ 20,000 women	≥ 40 hours	≥ 60 hours	≥ 5,000



# Chapter 12

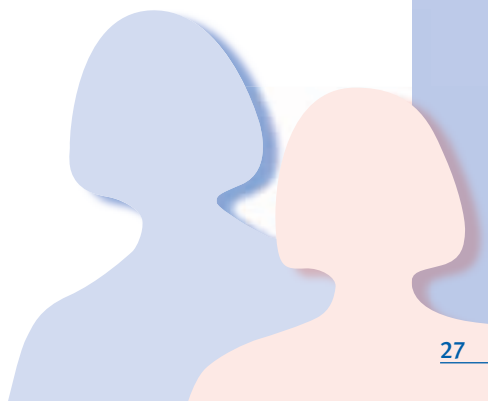
## Breast screening communication



- As screening involves inviting an apparently healthy woman to have a mammogram, women need to **know the pros and cons of participating** in screening so that they can make an **informed decision** about attending.
- All aspects of screening, its **benefits and imperfections must be explained clearly**, in an impartial manner to alleviate any anxiety a woman may have before, during or after participating.
- The information provided must be **honest, adequate, evidence-based, accessible, unbiased, respectful and tailored** to each woman's needs.
- All health professionals involved in screening must be **sensitive to cultural, linguistic, religious, educational and socioeconomic factors**.
- The **invitation letter and leaflet** should include information on the purpose of screening, the population targeted in the screening, how often screening is to be done, the benefits and disadvantages, whether the test is free or not, how to make or change an appointment, how to obtain and interpret the results, the possibility and nature of any further testing, and how women can access more information on screening and breast cancer.

## Potential quality indicators for communication in a screening programme:

	Yes	No
Telephone information service for women invited to screening	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Information on screening available in different formats	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Written information tested on target population for acceptability and readability	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Information materials for different ethnic groups or social needs groups	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Non-medical organisations involved in disseminating information	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Counselling protocols implemented	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Face-to-face information available on request	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Courses on communication organised for screening providers	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Women involved in developing and assessing materials	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Satisfaction questionnaires administered to target population	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Website available	<input checked="" type="checkbox"/>	<input type="checkbox"/>



# Annexes

*The annexes of the guidelines contain three EU documents on screening, reprinted in their entirety: the Council Recommendation of 2 December 2003 on Cancer Screening; the European Parliament Resolution on Breast Cancer in the European Union; and the Recommendation of the Committee of Ministers to Member States on Screening as a Tool of Preventive Medicine. These are key documents to lobby for quality assured screening and breast care programmes throughout the EU.*

## The Council Recommendation on Cancer Screening

This document contains **recommendations for Member States** to implement cancer screening programmes using a population-based approach with quality assurance at all levels. It calls for their implementation **according to the European guidelines**. Everyone who participates in screening is to be fully informed of the benefits and risks. The full array of diagnostic procedures, treatment, psychological support and aftercare must be available to those who have a positive screening test. It also requires that adequate human and financial resources be available to ensure appropriate organisation and quality control.

## European Parliament Resolution on Breast Cancer

The European Parliament Resolution on Breast Cancer of June 2003 makes demands to ensure that every woman in the EU, regardless of her place of residence, social status, occupation or education has access to **high-quality screening, treatment and aftercare for breast cancer**. It calls on the Commission to make the fight against breast cancer a health priority by implementing effective strategies for highest quality screening, diagnosis and aftercare. It asks member states to create, by 2008, the conditions required for a 25% reduction in the average breast cancer mortality rate in the EU and of reducing to 5% the disparity between member states (EU-15) in the 5-year survival rate. It also emphasises the need to establish effective **multidisciplinary breast units**.

***Note:** In October 2006, the European Parliament adopted a second resolution, the **European Parliament Resolution on Breast Cancer in the Enlarged European Union**, to reinforce the demands of the first resolution across the enlarged EU. It calls on Member States to ensure nationwide provision of **specialist breast units** in accordance with EU guidelines by 2016.*

In 2010, the European Parliament adopted a **Written Declaration on the Fight Against Breast Cancer in the European Union** (0071/2009) which serves as a reminder of the need to implement the European Parliament Resolutions on Breast Cancer. The Declaration calls for measures to ensure the implementation of **nationwide mammography screening programmes** that comply with the EU guidelines, **multidisciplinary specialist breast units** in accordance with the EU guidelines by 2016, and the development of a **certification protocol** for such units; the presentation of up-to-date, reliable **statistics** on breast cancer and the development of **national cancer registers**.

In 2015, the European Parliament adopted a **Written Declaration on the Fight Against Breast Cancer in the European Union** (0017/2015) to reiterate the need to implement the 2003 and 2006 European Parliament Resolutions on Breast Cancer and the European Guidelines for Quality Assurance in Breast Cancer Screening and Diagnosis. It calls for measures to ensure: the implementation of **nationwide breast screening programmes** that comply with the EU guidelines; the provision of **multidisciplinary specialist breast units** in accordance with the EU guidelines by 2016; that people with **metastatic breast cancer** have access to, and are treated in a specialist breast unit and that their ongoing needs for care and psychosocial services are co-ordinated by the SBU; that the **European Commission Initiative on Breast Cancer (ECIBC)** project will deliver an accreditation protocol for breast cancer services.

Written Declarations on the Fight Against Breast Cancer in the European Union

<http://www.europarl.europa.eu/plenary/en/written-declarations.html>

## Recommendation of the Committee of Ministers

The Committee of Ministers makes a number of recommendations regarding screening programmes and addresses their potential positive and negative effects. It points out legal and ethical issues such as **informed consent** to participate in screening, **protection of personal data and privacy**. Continued quality assurance during and after the implementation of any screening programme is emphasised, as is the need for **co-operation between screening and treatment programmes**.

For other information on EU documents, advocacy and breast cancer in general see:

- EUROPA DONNA – The European Breast Cancer Coalition [www.europadonna.org](http://www.europadonna.org)
- Breast Health Day [www.breasthealthday.org](http://www.breasthealthday.org)
- European Commission [ec.europa.eu](http://ec.europa.eu)

**Accreditation:** The process by which an authorising body gives formal recognition that another body is competent to carry out specific tasks.

**Breast-conserving surgery:** An operation that removes the breast cancer and saves the remaining healthy part of the breast.

**Certification:** The process by which an accredited body gives written assurance that a product, process or service conforms to specified requirements.

**Cytological sampling:** The removal and microscopic examination of removed cells.

**Cytoreductive surgery:** The surgical removal of part of a tumour that cannot be completely removed in order to enhance the effect of chemotherapy or radiotherapy.

**Ductal and lobular tumours:** The two most common tumour types.

**Epidemiology:** The study of the incidence and distribution of diseases and other health-related factors.

**Fine-needle aspiration cytology:** A procedure to extract cells or fluid from tissue using a needle with an empty syringe. The extracted cells or fluid are then analysed under a microscope.

**Histological sampling:** The examination of cell tissue structure under a microscope.

**Infiltrating tumour:** Abnormal cells that penetrate the tissue surrounding the area of origin of the tumour.

***In situ* tumour:** Abnormal cells that are confined to their site of origin without invading the surrounding tissue.

**Interval cancer:** A tumour that is diagnosed in the period between routine screenings.

**Mammogram:** An X-ray of all or part of the breast.

**Mammography screening:** Conducting mammograms in apparently healthy women in order to establish, as early as possible, whether or not they have breast cancer.

**Margin status:** The condition of whether or not the full area surrounding surgically removed tissue is tumour-free.

**Mastectomy:** Surgery that removes the whole breast.

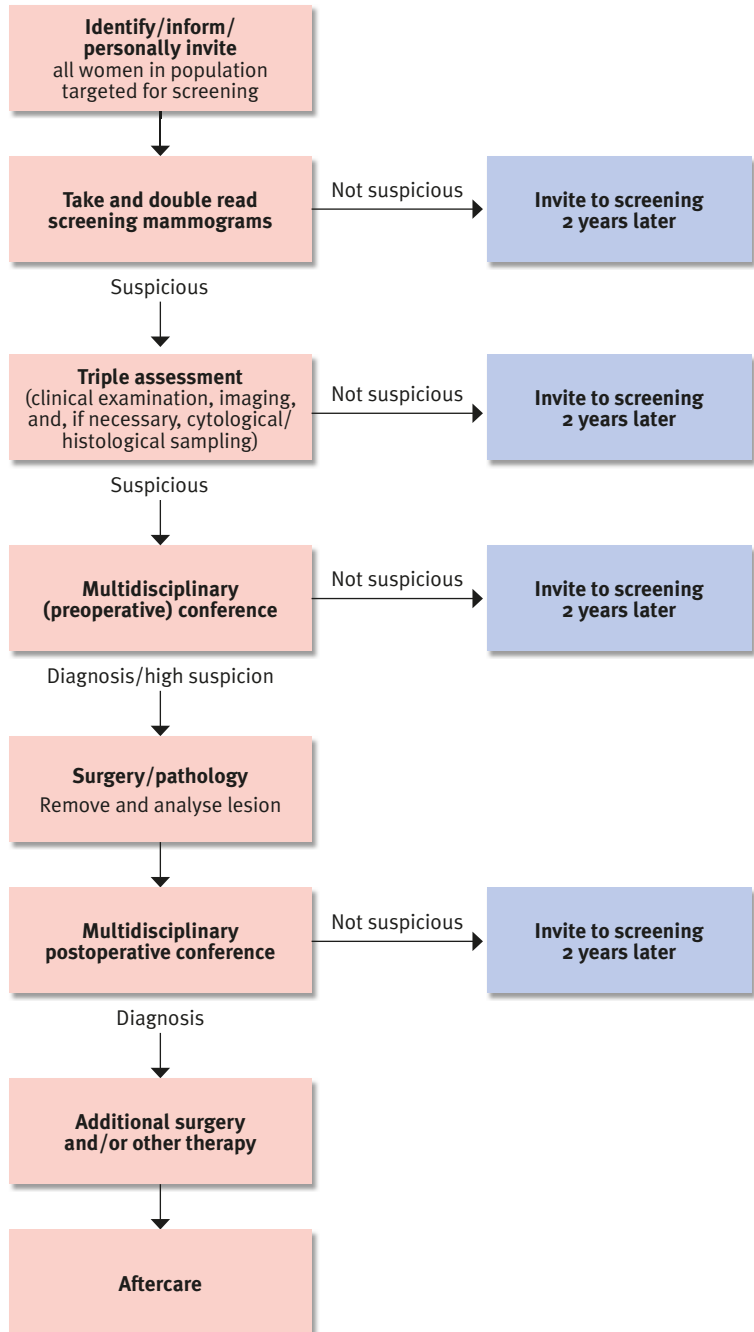
**Microcalcification:** Small abnormal calcium deposits seen on mammography that may indicate the presence of breast cancer.

**Multidisciplinary team:** A group of health care professionals from a variety of medical specialities who work together to diagnose and treat patients.



- Needle core biopsy:** Removal of a cylindrical tissue sample or part of a lump using a large, hollow needle. The tissue is then analysed under a microscope.
- Neoadjuvant:** Treatment, such as chemotherapy or radiotherapy, given before the primary therapy.
- Pathology:** The study and diagnosis of the structural and functional changes in cells, tissues and organs that underlie a disease.
- Population-based:** Identifying a target group based on general population registries.
- Radiography:** The use of radiation, especially X-rays, to produce a picture of internal body structures either on film or in a computer.
- Radiology:** The scientific study of the medical use of radiation, especially X-rays, for the diagnosis of a disease.
- Radiotherapy:** The use of controlled amounts of radiation, in the form of X-rays, gamma-rays or neutrons to kill cancer cells.
- Receptor status:** The condition of whether tumour cells are positive or negative for the oestrogen, progesterone and the HER2 receptors.
- Sentinel node procedure:** A biopsy technique involving the injection of blue dye and a radioactive substance to determine whether the cancer cells have spread to the lymph nodes.
- Symptomatic:** Women with apparent signs or symptoms of breast cancer, such as a breast lump.
- Target population:** A group that has been identified through epidemiological studies to meet the characteristics warranting invitation for screening.
- Triple assessment:** The combination of clinical examination, imaging and cell or tissue samples to determine a diagnosis.
- Tumour grade:** The measurement of the degree of abnormality of cancer cells in a tumour, graded I to III, with III being the most aggressive.
- Tumour type:** The classification of tumours as in situ, infiltrating, lobular or ductal.
- Vacuum-assisted needle core biopsy:** Removal of a tissue sample using a probe that applies suction. The tissue is then analysed under a microscope.
- Vascular invasion:** The penetration of cancer cells into the lymph or blood vessels.

## Description of the screening process



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The current, 4th Edition of the European Guidelines for Quality Assurance in Breast Cancer Screening and Diagnosis can be obtained through the European Commission bookshop. <http://bookshop.europa.eu>

The Executive Summary of the European Guidelines is also available at

[http://ec.europa.eu/health/ph\\_projects/2002/cancer/fp\\_cancer\\_2002\\_ext\\_guid\\_01.pdf](http://ec.europa.eu/health/ph_projects/2002/cancer/fp_cancer_2002_ext_guid_01.pdf)



Piazza Amendola, 3  
20149 Milan, Italy  
Tel: +39 02 3659 2280  
Fax: +39 02 3659 2284

Email: [info@europadonna.org](mailto:info@europadonna.org)  
[www.europadonna.org](http://www.europadonna.org)

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