Ensuring Progress on Best Practice
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The 8th EUROPA DONNA Pan-European Conference brought together more than 200 advocates from the Coalition’s 40 member countries with a focus on lobbying for the implementation of the European Guidelines for Quality Assurance in Breast Cancer Screening and Diagnosis. Following a special presentation on the guidelines, delegates also heard about the latest in diagnosis and treatment of breast cancer, ongoing clinical trials, health economics and access to new treatments, the needs of younger and older women with breast cancer, implementing specialist breast units, lifestyle factors and complementary medicine.

In the opening lecture, EU guidelines editor Dr. Nick Perry outlined the guidelines, the new contents of the fourth edition and emphasised their importance in lobbying for best practice. This session is now available in webcast format on www.europadonna.org. EUROPA DONNA also presented its Short Guide to the European Guidelines for Quality Assurance in Breast Cancer Screening and Diagnosis, a booklet highlighting the main points of the guidelines, as a key tool for lobbying.

Experts from the Netherlands Cancer Institute and the TRANSBIG research network presented innovations in breast cancer imaging, surgery, treatment and clinical trials. They stressed the need for multidisciplinary team assessment for breast cancer diagnosis and management and the importance of participating in clinical trials.

Other presentations covered the disparities between countries in the access to new drugs; the special needs of younger and older women with breast cancer and the lack of clear treatment guidelines for these age groups; and the influence of lifestyle factors in breast cancer and the use of complementary medicine to reduce side effects of treatment. Advocates were also given a special photographic tour of the award-winning specialist breast unit at St Barts Hospital in London, and advice on how to gain funding and set up a specialist breast unit in their countries.

A panel on guidelines implementation highlighted the experience with screening and the implementation process in Europe, Belgium, France and Slovenia and presented the new Short Guide to the European Guidelines for Quality Assurance in Breast Cancer Screening and Diagnosis. Advocates continued the discussion in a workshop dedicated to EU guidelines implementation using the “Short Guide”, and in other workshops on employment issues, age discrimination in screening and a meeting of the ED Young Women’s Network. The results of EUROPA DONNA’s surveys on hereditary breast cancer and tissue banking were also presented, as were the lobbying activities of ED Fora in Croatia, Iceland and Switzerland.

Held every two years, EUROPA DONNA’s Pan-European Conference aims to bring together advocates from all European countries to provide them with the tools required to lobby for breast cancer care in accordance with the EU guidelines. It is the only European breast cancer conference that is dedicated to breast cancer survivors and advocates and provides them with a special arena where they can compare and discuss experiences and strategies. This year’s conference was organised with the assistance and hospitality of the Netherlands Forum, whose members were present and helped as volunteers throughout the conference activities.

This report provides the full proceedings of the conference presentations.
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EU guidelines and their importance to advocates

The European Guidelines for Quality Assurance in Breast Cancer Screening and Diagnosis exist so that women can be guaranteed a service that at least meets minimum standards. The fourth edition of the EU guidelines, published in 2006, incorporates screening and diagnosis and contains new chapters on multidisciplinary aspects, specialist breast units, certification and communication, as well as new sections on mammography and locoregional treatment of breast cancer. The EU guidelines provide professionals, politicians and advocates with established targets, standards, outcomes and best practice. They are organisationally supported by the European Cancer Network, EUROPA DONNA, EUREF and EUSOMA and politically underpinned by the Council Recommendations and European Parliamentary Resolutions.

Introduction

The European guidelines and EUROPA DONNA are a perfect combination. ED is a very pan-European organisation with 40 member countries. The European guidelines are a major document and are becoming increasingly used and recognised. To carry out the necessary implementation of the guidelines, political and professional representation as well as much additional work is required. EUROPA DONNA can be very influential in the coming years to ensure that the ethos of the guidelines is followed.

The scope of European breast cancer

International Agency for Research on Cancer (IARC) statistics for 2006 indicate that there are 430,000 breast cancer cases and 132,000 breast cancer deaths per year in Europe. The lifetime risk of developing breast cancer is approaching one in nine. There has also been a demographic increase in breast cancer incidence due to the increasing ageing population. Increasing age itself holds a high risk for the development of breast cancer. At the other end of the scale, there has also been a rise in breast cancer cases in younger women.

Anxiety, morbidity and mortality are major problems with breast disease and breast cancer. These can be influenced through a variety of existing methodologies, expertise, specialisations, standards and outcomes, which can all be used to reduce the impact.

As mentioned above, the number of younger women affected with breast cancer is rising: 25% of women with breast cancer are premenopausal, compared with 20% in the past. At London Breast Institute, where there are 200 new breast cancer cases per year, 25% of the cancers occur in women under 45 years of age and 40% in those under 50 years. Younger women have more life years achievable. They may require a different emphasis, including family support and avoiding workplace discrimination.

Prof. Maurice Tubiana, Chairman of the pilot screening programme at Europe Against Cancer said, “Screening is worthwhile only if the increase in human life outweighs the economic and social costs (anxiety, unnecessary examinations) that it may produce.” He also pointed out that, “ultimately, progress depends not only on the dedication of professionals, but also on the courage of politicians and administrators.”

The European guidelines

The European guidelines are now in their fourth edition. The basic message of the guidelines is that women must be guaranteed a service that meets minimum standards. While aiming for all breast units to work at the highest level would be an excellent goal, it is practically of more benefit to women to ensure that lower quality services are increased in level.

Breast screening to detect breast cancer early and reduce mortality is a major public health intervention. Harm must be prevented by optimising the benefit–risk ratio of population-based screening by continuous quality improvement of the entire screening process. This must apply to all stages of screening, from invitations to treatment. More lives will be saved if standards are raised across the board, but a balance of sensitivity and specificity must be maintained. Screening must not do more harm than good. Outcome targets and a guide to best practice for service delivery must be provided.

Early editions

The first edition of the EU guidelines was published in 1993. Since the first edition, the number of pages and chapters have increased exponentially from 67 pages to 416 pages in the current edition. The third edition incorporated full chapters on radiography and radiology. Since they were quality assurance guidelines for mammography screening, there was discussion as to whether or not surgical guide-
lines should be included. We argued that surgery should be included, since follow-up with a surgeon is required for good management and detection of small cancers in screening. The surgical guidelines were incorporated in the third edition. With the introduction of standards to raise the quality of breast screening, it was then inequitable to exclude treatment of symptomatic women. Screening and diagnosis go hand in hand when the aim is to improve breast care for women.

The fourth edition of the EU guidelines
The fourth edition incorporates both screening and diagnosis. New chapters were added with the help of the European Society of Breast Cancer Specialists (EUSOMA), including chapters on multidisciplinary aspects of quality assurance in the diagnosis of breast disease and specialist breast units, as well as certification and communication. New sections within chapters are dedicated to digital mammography and locoregional treatment (Fig. 1).

Essential points of the EU guidelines chapters

Epidemiology
The target population for screening must be identified, so that knowledge can be gained about the women screened and the success of the programme can be evaluated. A successful programme reduces advanced cancers by 35% and reduces mortality from breast cancer by 25%. Standardisation of terminology and definitions is crucial, and population and cancer registries must be accurate. Without this knowledge, maximum use of the methodology cannot be applied. The main messages of this chapter and others are consistency, conformity and co-operation.

Physico-technical guidelines
The physico-technical guidelines set standards for imaging as image quality is crucial to detect small cancers and save lives. Ensuring the appropriate dose of radiation is essential. Large doses are counterproductive as they cause more harm than good. Acceptance testing of the imaging equipment should be conducted by trained medical physicists. Mammogram machines are a great investment in the health care of a large population of women, and they must therefore be tested for proper functioning. The manufacturer should not be solely responsible for testing. Trained medical physicists must perform the tests, ideally according to a centralised system of quality control. In the best systems every unit performs the quality control, and submits them to a central office where they are analysed and results are provided. The physicists must be trained in new technology, such as digital mammography, which is the trend for the future.

Radiography
Radiographers have the first and hopefully the only contact with the woman because only a small percentage of women should be recalled for further investigation. The acceptability of the screening programme is in the hands of the radiographers and all training and information must take this into account. Radiographers directly influence the image quality, including breast positioning, labelling of mammograms and correctly identifying the woman. They should have direct input into the quality control procedures on a daily basis. They are also a source of information for the patient. The woman being screened will ask questions about the process, the results, the technology, and radiographers must have the answers.

Radiology
Radiologists have a prime responsibility for image quality and screening. They should read at least 5,000 mammograms per year. There should be double-reading in decentralised screening programmes. The radiologist must be skilled in reading and assessment and take part in the review of interval cancers because it is a useful learning mechanism. With increasingly available non-operative diagnostic procedures, such as vacuum tissue sampling, radiologists must be experts in all such techniques. They must be able to detect a small cancer when it arises, whether or not there is help from computer-aided detection.

Multidisciplinary aspects
Modern breast care is multidisciplinary and all professionals involved must be part of the multidisciplinary team. Weekly multidisciplinary meetings should be held to discuss all patients that have undergone tissue sampling, all preoperative and postoperative cases, to ensure that the tissue excised is consistent with the preoperative diagnosis. All decisions and outcomes at these meetings should be documented and agreed among the team as a consensus decision.
**Pathology**

Pathologists must have standardised reporting data sets. Surgeons and oncologists must receive thorough reports including tumour size, grade, the margin status, extent, the tumour type and receptor status. Pathologists have to determine operative protocols with surgeons for marking and limitation of the margins.

**Surgery**

Surgeons should examine and counsel the patient prior to surgery, discuss all treatment options available to the woman and must be trained in sentinel lymph node procedures. They are crucial members of the multidisciplinary team and must participate in the multidisciplinary meetings as they are in prime charge of the management of the patient. Surgeons should support the inclusion of women, where appropriate, in clinical trials.

**Data collection and monitoring**

All aspects of a screening programme must be monitored and there should be a nominated staff member for data collection in every unit. Standard reporting forms are necessary and systems should be computerised so that data are easily available and extractable. All of these data must be in the public domain.

**Specialist breast units**

Specialist breast units comprise a fully trained professional team. There should be one unit per 250,000–300,000 population. Each unit must have a minimum of 150 new breast cancer cases detected per year, including 50 cancers per surgeon. There is to be a Nominated Clinical Director with responsibility and authority. Advanced Cancer Clinics should be held. The team should be extended to include other disciplines such as reconstructive surgery and palliative care.

**Training**

All medical staff should be trained and that training should involve an academic and clinical component. There should be a network of approved training centres and people should undergo continuing education. Records of every unit of staff training should be available for review.

**Certification**

Certification involves a certificate expedited by a team certifying that a unit is suitable. Accreditation is a wider process that guarantees that those organisations performing certification are working to proper standards. Self-regulation is not suitable due to local political and financial interest. In the guidelines, four European Reference Organisation for Quality Assured Breast Screening and Diagnostic Services (EUREF) certification levels are provided, including breast imaging units, breast assessment units, locoregional screening and European reference centre screening status. Site visits can be undertaken and are outlined in the chapter on certification.

**Communication**

Women must be able to make an informed decision to participate in screening. Information must be unbiased, honest and accessible. Staff must be sensitive to women’s needs, including their cultural, religious, educational and linguistic needs. The invitation letter must clearly define the process, the purpose for screening, the benefits and disadvantages of screening and contact details.

**Improved breast services for women**

We are striving to achieve high-quality screening and diagnosis and specialist breast units. Services must be centralised to ensure appropriate volume and cost-effectiveness. Audits and outcomes must be published. All of this requires professional acceptance and political impetus.

**Political recognition**

The European guidelines have political recognition through the Council Recommendation on Cancer Screening of 2003, which supports the implementation of screening according to the EU guidelines. The 2003 European Parliament Resolution on Breast Cancer calls for high-quality screening, treatment and aftercare for breast cancer and to create by 2008 the conditions for a 25% reduction in breast cancer mortality and reduce disparity in 5-year survival between Member States to 5%. It also states that effective multidisciplinary breast units should be established. More recently, the second European Parliament Resolution, of October 2006, calls for nationwide provision of specialist breast units in accordance with EU guidelines by 2016.

**Importance of the EU guidelines for advocates**

The EU guidelines provide advocates with a source of information establishing targets, standards, outcomes and best practice. It is professionally integrated, with the input of more than 200 people from 23 countries. They are organisationally supported by the European Cancer Network (ECN), EUROPA DONNA, EUREF and EUSOMA and politically underpinned by the Council Recommendations and Parliamentary Resolutions. The guidelines are in the public domain and can be translated.

The guidelines are a benchmark for advocates to raise awareness. They act as a support for lobbying activities, whether nationally or locally. The guidelines can be used to encourage research, to influence choice and advise on quality. Influencing choice is important, not only of women but of those financially supporting the system, such as insurance companies and government. Feedback on implementation of guidelines will be very useful and EUROPA DONNA with its extensive membership could help provide this information. EUROPA DONNA’s *Short Guide to the European Guidelines for Quality Assurance in Breast Cancer Screening and Diagnosis* will be essential to disseminate information and ensure this progress.

**Further reading**

Update and innovations in breast cancer surgery and radiotherapy

Specialist breast units offering all aspects of breast cancer screening, diagnosis and management improve the standard of care women receive while also improving the quality of life of patients and professionals working in the unit. Before any surgery or treatment is undertaken, a breast cancer diagnosis should be made and discussed in a multidisciplinary meeting. Breast-conserving surgery should always be considered, as should oncoplastic surgery to reconstruct the breast. If the tumour is too large for breast-conserving surgery, neoadjuvant chemotherapy should be considered to reduce the tumour size. If mastectomy is indicated, skin sparing mastectomy and reconstruction should be discussed. Microarray technology is able to reveal specific gene signatures in the tumour and will be a useful future tool in treatment decision making. Innovations in imaging and radiation will help to apply more tumour-targeted treatment.

Organising an efficient specialist breast unit

A breast unit is defined as a group of specialists in breast cancer who are situated within reasonable proximity to allow multidisciplinary working. The unit will see a sufficient number of cases to maintain the expertise of all its team members and will have at least 150 newly diagnosed breast cancers per year. It offers a full range of primary treatment as well as surgery, sentinel node procedure, oncoplastic techniques, radiotherapy and chemotherapy, as well as follow-up for patients. The core members of the multidisciplinary team include a surgeon, nurse practitioner, radiologist, pathologist, radiotherapist, oncologist and a breast care nurse. The patient is the central focus in every unit and communication is key.

The breast care nurse is a vital, equal member of the team with equal access to all information. She has a main role in providing information for the woman and giving support during diagnosis, treatment, admission for tests or surgery, final diagnosis, wound control and follow-up.

Other consultant members who also participate in the multidisciplinary team meetings include a plastic surgeon, psychologist, physiotherapist, clinical geneticist, lymphoedema therapist and a nuclear specialist.

The functioning of the clinic at the Netherlands Cancer Institute/Antoni van Leeuwenhoek (NKI-AVL) is shown in Figure 1. Thirty morning appointments are given on two week-days and women are informed that the process requires half a day. Women undergo mammography, ultrasound, and ultrasound-directed fine-needle aspiration (FNA) of tumours, suspicious tumours and nodes. Radiologists also examine the regional lymph node area, including the inferior and superior clavicular areas. A multidisciplinary meeting is held to discuss the results, after which the breast surgeon immediately gives the woman her diagnosis and treatment plan in the presence of the breast nurse, who can later provide additional information. If further investigations are required, the radiologist is available to do stereotactic biopsies that afternoon. If necessary, ultrasound-guided biopsies and core biopsies can be conducted for further examination of the tissues, particularly

![Fig. 1. Process followed at the NKI-AVL breast unit.](image-url)
if neoadjuvant chemotherapy is the preferred approach for treatment. Magnetic resonance imaging (MRI) can usually be provided within one week. If necessary, the other specialists, medical oncologists, radiotherapists and plastic surgeons, can be consulted the same afternoon.

The NKI-AVL unit’s experience since 1997 has shown that the breast specialist team helps to provide skilful diagnosis and treatment. A high throughput of patients is needed to maintain expertise and to be cost-effective. The patient is the centre of attention in the care process and the breast nurse is an essential team member. With a standardised and structured, short cyclic process, patients and health care workers know what to expect and what needs to be done. Specialist breast units improve the quality of life of the patient and of the multidisciplinary team members. A recent study from the UK has confirmed that professionals working as part of an organised, structured breast team have an improved quality of life.

**Imaging innovations**

There have been a number of innovations in imaging techniques, including contrast-enhanced MRI, 3-D imaging, digital and computer-aided detection mammography, digital tomosynthesis, 3-D ultrasound and dedicated positron emission mammography (PEM). If a patient is scheduled for breast-conserving surgery or for neoadjuvant chemotherapy, an MRI of the breast provides useful images.

**Tumour tissue innovations**

Using tumour tissue from core biopsies, a full gene array of the tumour tissue can be performed. It is expected that in 5–10 years analysis of tumour tissue will indicate the metastatic potential of the tumour. Tissue analysis also provides information on the hormone sensitivity, the HER2/neu status, the vascular endothelial growth factor (VEGF) status and the p53 status, which are all innovative targets for therapy.

**Breast cancer surgery**

It is proven that better local control leads to better survival. Quality of life improves and costs are reduced with less invasive procedures and with treatment that has fewer side effects. Quality of life also improves with better cosmetic outcome. Information on prognosis allows patient-tailored treatment.

**Lymph node status**

A main component of any breast cancer diagnosis involves determining the lymph node status. As a first step, an axillary ultrasound and FNA cytology must be performed. This is reasonably cost-effective and one-third of the positive nodes can be identified.

The second step involves the sentinel node procedure which can be considered a standard of care. If a patient is found to be node negative clinically or on ultrasound and she has inoperable breast cancer, a sentinel node biopsy should be performed. It is a safe procedure which identifies the same percentage of positive nodes as axillary dissection, with less morbidity. A Cochrane-like review was conducted of 40 studies in which nodes were negative according to the sentinel node procedure and a wait-and-see policy was followed. At 3–4 years it was found that in the more than 14,000 patients who underwent this treatment, the risk of recurrence in the axilla was 0.36%. Sentinel node biopsy is therefore a safe procedure.

A similar study of axillary lymph node dissection found the relapse rate to be 8.8–2.3%. This may be due to the fact that the data series were older and the tumours more advanced than currently encountered.

Sentinel node procedure should be performed by an experienced team. The surgeon should have done at least 20 cases, and studies indicate that they should conduct at least six procedures per week. Performing fewer cases is associated with a less than 85% identification rate. A nuclear physician must perform the lymphoscintigraphy and a pathologist must examine the lymph nodes. With this team there should be an identification rate of over 95% and a less than 5% false-negative rate.

Using sentinel node biopsy with a combined tracer technique incorporating blue dye and lymphoscintigraphy is also effective. In the Netherlands, 95% of patients undergo this technique.

In the case of micrometastases of 0.2–2 mm, the axilla should be treated. If the micrometastasis is smaller, a wait-and-see policy is generally advocated and safe.

**Surgical update**

Breast-conserving surgery should always be considered, unless the tumour is too large in relation to breast size, extensive intraductal carcinoma has been completely excised, and if the woman is younger than 35, due to high risk of relapse. Oncoplastic surgery should always be conducted. Every surgeon should strive to optimally reconstruct a breast after removing part of it. Failing to reconstruct the breast allows the cavity to fill with fluid, which can induce subsequent fibrosis and induce a larger target volume for the radio-oncologist, which in turn induces more fibrosis. Removing only the affected area is no longer standard of care. While breast-conserving surgery should always be considered in operable breast cancer, there are some limitations. If in order to perform a complete resection with free margins the portion of the breast to be removed is too large for a good cosmetic result, other options should be considered, such as neoadjuvant chemotherapy to attempt to reduce the size of the tumour, or symmetrizing the other breast.

In cases where mastectomy is the better option, the procedure should be skin sparing and the patient should always be informed of the possibility of breast reconstruction. Unfortunately, even today, patients are not always offered the opportunity of immediate reconstruction. It has been shown to be oncologically safe, to have the same complication rate as no reconstruction, and a better cosmetic outcome. However, if radiotherapy is given after breast reconstruction there may be more complications and somewhat worse cosmesis. This must be discussed with the woman and if radiotherapy is indicated following mastectomy, reconstruction could be offered at a later date.

Breast-conserving surgery can be improved through image-guided techniques such as radioguided occult lesion localisation (ROLL) for nonpalpable, screen-detected cancer. This technique involves injecting radiocolloid into the lesion. This obtains the sentinel node scan and the tumour can be excised by removing the radioactive area. We improved our free margins rate from 80% to 90% with this procedure.
Breast surgery can also now be done under regional anesthesia rather than general anesthesia, which reduces pain for the patient and allows her to go home on the day of the surgery or the day after.

A new system used in brain surgery is also being tested in breast surgery. MRI-guided tumour localisation helps to increase the fraction of complete excisions and to improve centring of the tumour in the excision. Using an MRI taken the previous day, fixed points in the breast can be identified, an infrared system completely localises the breast, and the tumour can be located by a probe. This technique may be used in the future.

Radiation therapy
Modern radiation techniques allow better targeting of the breast and spare other organs. In left-sided radiation the radiation field can reach the heart, and an excess rate of cardiac death has been shown for left-sided radiotherapy. Intensity-modulated radiotherapy (IMRT) is a new technique using multiple leaves that allow the radiation field to be directed more to the breast and less to the heart and lungs. There are also imaging techniques in which a cone beam CT-guided accelerator permits visualisation of the radiation beams. Another very simple technique is the breath-hold technique in which the patient holds her breath thereby pushing the heart outside the radiation field.

Effect of treatment and age on outcome
The European BOOST trial is now being conducted to determine whether or not a higher radiation dose can result in a higher cure rate. More than 5,000 patients were randomised to receive a standard dose of radiation or a 16 Gy boosted dose after breast-conserving surgery. It was found that the 16 Gy increase in radiation dose decreased the relapse rate by a factor of 2.

Results with partial breast irradiation are still not convincing. However, in the future it may be an alternative to full breast irradiation in selected patients. Randomised trials need to define precisely which patients can benefit from partial breast irradiation.

After 20 years of study, the Early Breast Cancer Trialists’ Collaborative Group (EBCTCG) has shown that better local control leads to better overall survival. While this observation may seem logical, long-term studies have been required to prove the hypothesis, since tumours take time to relapse and metastasise. For every four local recurrences avoided, one breast cancer death can be avoided.

It has been observed that younger women, particularly those under age 40, have a greater risk of relapse after breast-conserving surgery. Research is being conducted to determine which genes are involved in this high failure rate. One of the possibilities being explored is the wound-response signature, which comes from an older hypothesis that tumours are wounds that do not heal. This is based on similarities in different processes that occur both in a wound and in cancer, such as angiogenesis, proliferation and matrix remodelling. From the tissues surrounding wounds a gene signature has been extracted that shows differences in speed of healing. In breast cancer, using the wound-like expression genes it has been possible to significantly distinguish between patients who did and did not develop a local recurrence. While more must still be learned, this offers the possibility that gene signatures in the tissue of the tumour or surrounding area may indicate which patients have a high risk of relapse and may be better candidates for mastectomy.

In summary, an increased dose of irradiation reduces the incidence of local recurrence in young and older patients. Microarray technology will guide individual indications for radiotherapy and the required radiation dose. IMRT and image-guided radiotherapy will safely deliver the required radiation dose. Partial breast irradiation may be indicated in selected patients. These innovations in imaging help to apply more local treatment, and thus improve quality of life and survival.

Further reading
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New advances: targeted therapies and clinical trials, including MINDACT

A number of revolutions in breast cancer management have occurred over the years, leading to a common shift from maximum treatment to tailored treatment. The Breast International Group (BIG) and its TRANSBIG consortium for translational research, of which EUROPA DONNA is a member of the Steering, Ethical-Legal and Spreading of Excellence Committees, have been conducting large, prospective trials that have helped to shape how breast cancer is treated today. Some of the most recent trials aim to determine who needs adjuvant treatment and which types of cancer benefit from which types of treatment. Now ongoing, MINDACT is TRANSBIG's first trial and aims to use microarray technology to identify tumours with a genomic signature indicating a low risk of distant relapse and test the hypothesis that these women can be safely spared the inconvenience and morbidity of adjuvant chemotherapy. Newer targeted treatments include HER2-targeting drugs such as trastuzumab and lapatinib. Increased co-operation and participation in clinical trials can help to further decrease the mortality and morbidity from breast cancer.

Breast cancer: the magnitude of the problem

The magnitude of the problem of breast cancer is well established. One in eight women in the Western world will have breast cancer in her lifetime. Two-thirds of deaths from breast cancer are due to distant metastasis.

Despite these numbers, some specialists in other fields deny the magnitude of the problem. Opponents of breast cancer screening can rest assured that while screening programmes may be expensive, treatment of late-stage breast cancer is much more costly than treating early-stage disease. Data from the National Institutes of Health in the USA from some years ago, already showed that treatment of early-stage breast cancer costs $12,000 US per patient, without adjuvant trastuzumab, while treatment of late-stage disease costs $345,000 per patient.

Revolutions in breast cancer management

There have been a number of major changes that have led to a different approach to breast cancer management over the years. These have included changes in scientific dogmas regarding breast cancer, social changes, breast cancer screening and the development of effective systemic treatments. We are currently in this last phase of this revolution, where translational medicine takes central stage, including the clinical application of genomics and proteomics.

The scientific revolution

There have been two major advances in the scientific understanding of breast cancer. Firstly, excessive treatment is not necessary: “more” is not always better. Secondly, we have learned that breast cancer is not a local but a systemic disease, which means that the distant metastases cause the death of the patient.

More is not always better

Past practices of superradical mastectomy and then radical mastectomy with axillary dissection have been replaced by modified radical mastectomy and in the last years by breast-conserving surgery and sentinel node biopsy. This has helped to greatly increase quality of life without any compromise on mortality reduction through a decrease in side effects and sequelae such as lymphoedema. Doses of radiotherapy have been greatly reduced and now in development is intraoperative radiotherapy which is applied in one day rather than daily over a six-week period.

Breast cancer as a systemic disease

The knowledge gained regarding breast cancer as a systemic disease, rather than a local disease, is likely the most significant change in scientific dogma and led to a drastic change in breast cancer management. When it was believed to be a local disease, treatments were locally aggressive, and hence very mutilating surgery and strong radiotherapy were conducted. When breast cancer was established as a systemic disease, the aims of treatment and research shifted to attempting to identify efficacious systemic treatments. Two examples resulting from this effort are the anthracyclines and tamoxifen, the latter being one of the drugs that has saved more lives throughout the world in all medical disciplines, not just oncology.

The social revolution

The social dogmas of breast cancer have changed and people can now speak freely about the disease without feeling shame or guilt. The role of women in society and in medicine has
also changed and has had a strong impact on the management of breast cancer. In 1970 less than 7% of all physicians in the United States were women. All the members of the American Cancer Society Breast Cancer Advisory Board were men. In Europe these figures were only slightly better and began to improve in the 1960s.

Population-based screening
The importance of widespread screening and what it has accomplished in the early detection and improved mortality rates is well established.

The “omics” era and translational medicine
The latest revolution in breast cancer management began with the sequencing of the human genome. We have gone from the microscope to the “genoscope”, which is the technology used to identify the whole genome of a tumour, or the genes that determine the biology of the tumour. In the future a “proteoscope” should be able to examine proteins and how they work inside the body. Imaging has also greatly evolved and helped us to better understand the biology of breast cancer.

Translational research is like a bridge between the laboratory and the clinic. In the past and still today, there is little communication between the laboratory scientists and clinicians, which leads to laboratory science possibly not investigating clinically relevant issues. This lack of communication also delays the application of the research findings to the patient. For instance, the time between drug discovery and its use in the clinic was 15–20 years. Through the application of translational research this has now been reduced to less than 10 years and in some cases to about 5 years.

Current breast cancer management
Current breast cancer research and management has three main goals: treatment individualisation or tailoring; the identification and use of new treatments that are more effective and have fewer side effects; and improved quality of life and survivorship.

Tailored treatment
There are several interrelated reasons for treatment tailoring. Current therapeutic strategies involve surgery, radiotherapy, biological therapy, chemotherapy and hormone treatment. A great majority of women receive a combination of these treatments. Overtreatment is common due to the need to treat the cancer in its early stages and thus avoid metastatic disease, which is incurable. As a result, when there are doubts, physicians tend to treat, which leads to the problem of overtreating early disease.

It is now known that regarding chemotherapy, the treatment benefit varies according to the type of chemotherapy used and the level of risk of the patient. Very high-risk cases normally derive the greater benefit from chemotherapy, provided that the tumour responds well to that treatment.

Unfortunately, chemotherapy also has side effects. While there are short-term side effects (e.g., hair loss) which occur during treatment and disappear when treatment is discontinued, some long-term side effects may affect the patient for the rest of her life. Some of the long-term risks include secondary cancers, cardiac toxicity, early menopause and decreased cognitive function. The current aim is to identify more effective regimens with fewer side effects, and to identify which patients will benefit from chemotherapy.

Results based on microarray technology also indicate that treatment must be individualised for each patient. Using microarray technology, many tumours and their genes were analysed to determine similar characteristics between tumours and thus group them into subtypes of breast cancer. Different groups throughout the world, in the USA and in Europe, undertook this task and concluded that breast cancer is not just one type of disease, but at least four or five diseases. In simplified terms, breast cancer can be mainly divided into endocrine-responsive (hormone receptor positive) and endocrine non-responsive (hormone receptor negative) diseases, and different subgroups exist within these two categories. Microarray technology has helped to prove something that was already known in the clinic: that there are several types of breast cancer. They therefore cannot be treated identically: different biology requires different treatments.

Tailored treatment is also necessary as it helps to reduce treatment costs. Costs of breast cancer treatment have gradually increased with the introduction of new therapies. Prescribing every treatment type for every tumour type overextends resources that can be dedicated more effectively to tailored treatment.

Two main questions need answering: Who needs treatment and which treatment is best? More precise prognostic factors need to be developed; the best treatment for each individual must be determined; and predictive factors must be identified. This can be accomplished through clinical research, and high-quality clinical trials with higher patient participation. For this new generation of trials patient selection is very important. A case in point is the development of trastuzumab (Herceptin®). If this treatment had been given to all breast cancer patients rather than a selected group, it would have been considered to be ineffective and a very important breast cancer treatment would have been lost.

BIG and TRANSBIG
In the past, breast cancer clinical research was limited by fragmentation and lack of collaboration. Hence many small research groups would attempt to answer the same question with significantly underpowered trials. To tackle this fragmentation, the Breast International Group (BIG) was founded in 1996 as a Belgian-based non-profit organisation composed of world renowned national and international research groups in breast cancer. BIG is currently chaired by Drs. Martine Piccart and Aron Goldhirsch, and co-ordinated through a central secretariat in Brussels, Belgium. BIG now encompasses more than 35 research groups in 36 countries, with more than 75,000 patients entered in BIG studies. Examples of some trials run under the BIG network include the HERA trial (Herceptin® Adjuvant trial) and the BIG-FEMTA (Femara® Adjuvant trial).

As the same fragmentation of research was found to exist in translational research, the successful BIG model was expanded and a complementary network, TRANSBIG, was founded. TRANSBIG involves the collaboration of 40 partners in countries in Europe, Australasia, Canada, South America and South Africa. The European Commission has awarded this project partial funding under its
NEW GENERATION OF TRIALS CONCEPT

<table>
<thead>
<tr>
<th>Empirical approach</th>
<th>Tailored approach</th>
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</thead>
<tbody>
<tr>
<td>Large trials comparing treatments A vs. B vs. C</td>
<td>Tailored trials asking biologically relevant questions</td>
</tr>
</tbody>
</table>

**Successful transition?**

- Reinforced dialogue with scientists
- Reinforced dialogue with surgeons, pathologists, radiologists
- New models of collaboration with industry
- Independent funding

**Fig. 1. The tailored approach to clinical trials.**

### The MINDACT trial: identifying better prognostic factors

MINDACT stands for Microarray for Node-Negative Disease May Avoid Chemotherapy. It has been recently announced that this name will change to Microarray for Up to Three Positive Nodes May Avoid Chemotherapy, but the acronym MINDACT will be retained. Starting in 2008, the trial will include women with up to three positive nodes, due to the strong data showing the same results for nodes 1-, 2- and 3-positive disease as for node-negative disease. It will use microarray technology to prognostically classify early-stage breast cancer patients into high and low risk of distant relapse and compare this to traditional pathological methods. MINDACT aims to prospectively validate a 70-gene poor-prognosis signature identified by researchers at the Netherlands Cancer Institute using microarray technology. It is the first trial in the world to use microarray technology to define which patients require adjuvant chemotherapy. If the assumptions are correct, the trial will better identify women who will benefit from chemotherapy, and will therefore reduce toxicity, side effects and costs. It will be a benefit for patients and for society.

Dutch scientists used the new microarray technology to divide patients with breast cancer who had not received adjuvant treatment into two distinct groups. The patients with a good gene signature showed very good survival. At 10 years, 96% were alive with no adjuvant treatment. Those with a poor gene signature had a 50% chance of survival at 10 years. The researchers transformed this new tool into an easy-to-use test using 70 genes (MammaPrint™) which are highly informative about the tumour biology. Afterwards they compared the new tool with current clinical pathological methods, such as patient age, menopausal status and tumour characteristics (size, lymph node status, grade, receptor status) to determine the risk of recurrence and the need for chemotherapy. They found that both methods were effective at identifying the high-risk, but not low-risk patients. However, it was seen that the new tool identified those at low risk of recurrence and those not requiring chemotherapy. These results were validated. During this process, other signatures appeared, and it was found that there were not many genes in common. For example, between the Rotterdam signature and the Amsterdam signature there are only three genes in common. Yet, while the genes are different, the pathways to which they belong, i.e., the biology of the tumour, is the same. They showed that these tumours are very highly proliferative and may respond better to chemotherapy.

Based on these findings, the MINDACT trial was initiated. In the trial design, the risk of tumour recurrence is analysed using the traditional clinical pathological method and the 70-gene signature. If a patient is classified as high risk according to both methods, she should receive chemotherapy. If both methods indicate a low risk of relapse, then chemotherapy is not prescribed. However, if one test indicates high risk while the other indicates low risk, the patient is randomised to follow either the genomic test or the traditional test and to receive chemotherapy or not to receive chemotherapy (Fig. 2). If done correctly, 10–15% of the women will be safely spared chemotherapy. In the process of the trial, frozen material, paraffin material and blood are being collected from all the trial participants, which may help to identify more tools for the future.

With the help of EUROPA DONNA, we have created an interactive DVD, in several languages, explaining various aspects of breast cancer, microarray technology and the MINDACT trial to assist patients in making an informed decision to participate in the trial.

### HER2-targeting drugs

The oldest and one of the best targeted therapies discovered was tamoxifen. Hormonal therapy is the oldest form of targeted therapy; the receptor is the target, oestrogen is the ligand, and the drug blocks the target.

Later, other receptors, such as the HER2 receptor, were discovered. Trastuzumab (Herceptin®) was proven to increase survival in the metastatic setting, and was thus used as adjuvant treatment. This was the first time that scientists were able to work together in a subgroup of patients (only one in four women have HER2-positive disease). They conducted just four or five trials throughout the world, and quickly. All the trials showed the same results: trastuzumab was associated with about a 52% reduction in the risk of relapse and a 33% reduction in the risk of death. However, there was much misinformation particularly in the press, such that some women tried to receive trastuzumab therapy even if they had HER2-negative disease and were therefore not eligible. Enthusiasm about results must be balanced and not give hopes where they do not exist.

Trastuzumab shows an important benefit in HER2-positive disease, yet even in these cases only about 50% respond to this treatment. While it is a great advance, it is not a cure. It has a risk of side effects, such as cardiotoxicity, albeit mainly reversible. There is now more bal-
anced enthusiasm about trastuzumab and other targeted agents.

A new drug, lapatinib, has been developed. It has a similar mechanism to trastuzumab (i.e., it blocks the HER-2 receptor) but is administered orally rather than intravenously, as well as some other distinct characteristics.

A new trial, the ALTTO (Adjuvant Lapatinib and/or Trastuzumab Treatment Optimisation) study, has been designed to compare the efficacy of lapatinib and trastuzumab, or their co-administration. It is a co-operative trial between Europe (through the BIG consortium) and the USA (through the US Breast Intergroup) and is to include 8,000 patients in 2–3 years.

Conclusions

Targeted treatment is not free of side effects, some of which include diarrhea, fatigue, proteinuria, hypertension, bleeding and thrombosis episodes, nail and skin toxicity. We therefore need to continue to work to develop new treatments with fewer side effects. We also must work together to increase the number of patients who participate in clinical trials. Even in the Western world, in the USA, less than 10% of patients enter clinical trials. One motivating factor is that the mortality from breast cancer has steadily decreased since the 1990s. For this we can thank all those working together to treat this disease and women who have participated in trials.

Further reading

- Cardoso, F. Show me the genes… I will tell you who/how to treat!. Viewpoint article. Breast Cancer Res 2005, 7: 77-9.

Fig. 2. MINDACT trial design.
Health economics issues and access to new treatments

The 2007 study *A Global Comparison Regarding Patient Access to Cancer Drugs* revealed that patients have unequal access to innovative cancer drugs. It examined access to 67 new cancer drugs in 25 countries. Austria, France, Switzerland and the USA were found to have the highest uptake of new cancer drugs, while at the opposite end of the spectrum were New Zealand, Poland, Czech Republic, South Africa and the UK. A large divide between countries also exists in public spending on cancer drugs and cancer research. Patients worldwide should know their treatment alternatives and also expect a rational policy governing their access to new drugs. All patients should have equal and early access to innovative treatments and the introduction of innovative treatments must be managed carefully. Research into patients’ access to therapy is an important component of cancer research.

**Introduction: health economics**

Health economics involves the application of the discipline of economics to the topic of health resources and their allocation. The 2007 study on patients’ access to new cancer drugs found that most countries have few data on the amount of their resources spent on cancer. Health costs are widely discussed, but not in a systematic fashion.

With regard to spending, most industrialised countries spend 8–9% of their total resources on health care. It is interesting to determine the amount being spent and how spending choices are made. Since resources are limited, it must be carefully decided where they should be allocated. Health economics involves how resources are spent to improve health.

Health is one of the most important aspects of any society and resources should be spent to improve it. Living conditions greatly affect health care services: those with poor health care are often those with poor living conditions, low income and low education. General economic progress has a large influence on health care.

Health protection and early detection are very important, as are treatment and rehabilitation. The resources available must be balanced between these areas. To do this, investments must be made in the public and private sectors.

**The Karolinska Report**

The 2007 study, *A Global Comparison Regarding Patient Access to Cancer Drugs*, is an update and extension of the 2005 European Karolinska Report. It aimed to examine access to cancer drugs in 25 countries, including 19 European countries, as well as the United States, Canada, Japan, Australia, New Zealand and South Africa, covering a total population of 984 million people. The European countries included in the study constituted 76% of the European population (447 million). The report aimed to determine the current status of the evolution of treatments, to review the advances in cancer management, to identify obstacles to access, and discuss options for improvement. It particularly examined economic factors such as health technology assessment, reimbursement and funding mechanisms.

The study was based on the link between medicine and economics. It focused specifically on oncology drugs, the knowledge and availability of which have increased in recent decades. Approximately 70 oncology drugs are now available and 3,000 are in development. The report examined the link between medical and economic development, particularly with regard to how economic factors determine patients’ access to treatment. In addition to the non-economic factors that influence access to treatment, such as availability of physicians and hospitals, economic factors are increasingly determining the type of treatment offered to patients. Whereas most societies have created health care systems that do not depend on users’ income, the growing influence of economic factors challenges the foundations of many public health care systems.

**The burden of cancer**

The incidence of cancer is increasing with the ageing population. While diagnosis is made early and outcomes have significantly improved, cancer still accounts for about 7 million deaths annually worldwide. Cancer accounted for 16.7% of “healthy” years lost in the EU in 2002 and 12.5% in the USA and Canada.

Next to mental diseases, which carry the heaviest economic and health burden, cancer is now the second most burdensome disease. It now replaces cardiovascular disease, except in the USA where cardiovascular disease incidence remains high. During the Dutch presidency of the EU, a report was published on the development of “priority medicines” for areas with a high health burden. Cancer is a priority area, both in terms of mortality and in the combina-
tion of mortality and morbidity. The latter is referred to as disease-adjusted life years (DALYs), which is a measure used by the World Health Organization, the World Bank and other organisations to set priorities within the health care sector.

Breast cancer incidence

Breast cancer incidence has increased mainly due to detection through screening and the changing composition of the population. Despite this, cost has not greatly increased because of the rises in productivity gained through surgery and radiotherapy. Regarding mortality due to breast cancer, the United Kingdom shows much higher mortality rates than Norway, Poland, Portugal, Spain, Sweden, Switzerland and the USA, though they are decreasing. Across these countries, mortality began to drop with the introduction of tamoxifen, which became available before the widespread implementation of screening programmes.

Direct and indirect costs of cancer

Available statistics on cancer spending in the USA indicate that 5% of all resources is spent on cancer in the USA, a percentage that has remained constant for the last 30 years. Cost of hospitalisation is a dominating cost item due to surgical treatment and radiotherapy, which require a large hospital infrastructure. Indirect cost in terms of lost production is more than double the direct health care costs. The rising incidence of breast cancer among younger women will have repercussions due to their lost productivity.

The study estimates the amount of resources spent on cancer. As shown in Table 1, in Europe cancer spending per capita is €125 and it accounts for 6.4% of the total health care costs.

Table 1. Direct costs for cancer care in selected countries in 2004. Costs are purchasing power parity (PPP) adjusted.

<table>
<thead>
<tr>
<th>Country</th>
<th>Total million Euro</th>
<th>Per capita in Euro</th>
<th>Share of total health care costs (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Europe</td>
<td>56,664</td>
<td>125</td>
<td>6.4</td>
</tr>
<tr>
<td>Germany</td>
<td>12,108</td>
<td>147</td>
<td>6.6</td>
</tr>
<tr>
<td>United States</td>
<td>63,321</td>
<td>212</td>
<td>4.7</td>
</tr>
<tr>
<td>Canada</td>
<td>5,013</td>
<td>157</td>
<td>6.7</td>
</tr>
</tbody>
</table>

A recent analysis by Lidgren et al. examined the cost of breast cancer in Sweden in 2002. There are about 7,000 annual cases of breast cancer in Sweden and therefore 80,000 women living with breast cancer. Breast cancer screening cost about €21 million in 2002. The total direct cost for diagnosis, treatment and palliative care was almost €96 million. However, indirect costs totalled more than €225 million. This includes the time off work that breast cancer patients require either temporarily or for early retirement, as well as loss of productivity due to early mortality. As the indirect costs are more than double the direct costs, understanding the issues behind them is very important. Improved prevention and treatment of breast cancer may help to eliminate a large extent of the indirect costs.

Drug development and sales

In the sales and development of cancer drugs and the influence on cost, there is a trend toward increasing drug cost until a drug loses its patent protection. Today tamoxifen costs a fraction of what it cost in the 1980s. In the same way, one of today’s top selling breast cancer drugs, trastuzumab, will in the future show a drop in price and thus a significant reduced impact on cost. Although overall drug costs increase with the introduction of new treatments, the benefit gained from the new drug must also be considered. Figure 1 shows the difference in cancer drug spending in 22 different countries.

Drug cost in perspective

Since 1995 there have been about two new cancer drugs available every year and the drug costs have increased 15–20% per year. Yet 3.5–7% of the total drug expenditure is on cancer drugs, which account for a minor, but growing, part (10–15%) of the total cancer care expenditure.

The total global public (government and charity) investment in cancer drug research and development is about €7 billion annually, €5.1 billion in public spending in the USA, €1.4 billion in Europe and €0.5 billion in other countries. From 1995 to 2004, 14% of all drugs approved in the USA were cancer drugs. Private investment by the pharmaceutical industry and others is about €6 billion. Europe should reconsider its positioning in terms of public finance of clinical research. Funds need to be invested to ensure that new drugs on the market are used correctly. The UK and Sweden have rather high public spending in cancer research, but they are far behind the USA.

Drugs in the cancer field command higher prices today, which means that it also is more profitable for the pharmaceutical industry to invest in this field. It is estimated that 15% of the entire research expenditure by the pharmaceutical industry is spent on cancer research. In general, the private industry invests more than the public sector in new drug development. When new drugs reach the market, they provide an opportunity as well as a cost. This opportunity must be handled with care.
Inequities between countries in the uptake and use of cancer drugs

The Karolinska Report examined the access to 67 innovative cancer drugs, recognised as important advances in cancer. These included trastuzumab and aromatase inhibitors for breast cancer; bevacizumab and cetuximab for colorectal cancer; erlotinib and pemetrexed for lung cancer; rituximab for non-Hodgkin’s lymphoma; and imatinib for chronic myeloid leukaemia.

Analyses of the uptake of aromatase inhibitors (combined data for anastrozole, exemestane and letrozole) and of trastuzumab reveals that the USA has the most rapid uptake of these drugs, followed by France. Generally, Austria, France, Switzerland and the USA are the leaders in the use of new cancer drugs, with France replacing Spain among the top four since the 2005 report was published. In 2004 France applied a new separate reimbursement for costly molecules, if they are used according to best practices, to ensure equal access. This has increased access to new cancer drugs in this country. Lower and slower uptake of new cancer drugs occurs in New Zealand, Poland, Czech Republic, South Africa and the UK. Patients worldwide should know their treatment alternatives and also expect a rational policy governing their access to new drugs.

Role of economic factors in determining access to new drugs

Countries with a low GDP and health care expenditure per capita have less access to new drugs. A significant problem exists in some of the new EU Member States, particularly in the central and Eastern European countries. Though they are EU members, they have very little access and use of new, expensive drugs. Bulgaria has a $600 US per capita health care expenditure, compared to $6,000 in the USA. The two countries pay the same price for drugs. These differences must be better examined as a number of EU countries have a similar level of health care expenditure to Bulgaria.

A positive reimbursement decision or guidance for use is important but not decisive in drug uptake. However, as shown with the change in the reimbursement scheme in France, positive reimbursement is important because if governments do not cover the costs of new drugs, very few patients can personally afford them. The funding mechanisms for inpatient and outpatient use in hospitals is also a very important explanatory factor.

Cost-effectiveness studies are becoming routine for decisions about reimbursement. To be included in the reimbursement system the drug must pass an acceptable threshold per quality-adjusted life year. Resources are required to assess these drugs and resources must be available for those positively assessed. Several studies such as Lidgren et al. (2007), for example, have examined the cost-effectiveness of trastuzumab in adjuvant treatment compared with standard treatment, and found it to be cost-effective in terms of cost per quality-adjusted life year.

Explaining changes in mortality and survival

The part of the Karolinska Report and the updated study that examine the association between access to treatment and cancer survival and extended study have been controversial, though they follow a method economists use to analyse the impact of access and utilisation of new drugs on changes in mortality due to cancer and in survival over time. It is a method used routinely in other disease areas. A recent study by Ford et al. in coronary heart disease published in the New England Journal of Medicine showed that approximately half the decline in deaths from coronary heart disease in the USA from 1980 to 2000 may be attributable to reductions in major risk factors and approximately half to evidence-based medical therapies.

Another study by Berry et al. on the effect of screening and adjuvant therapy on mortality from breast cancer examined the contribution of mammography screening and adjuvant treatment to the reduction in breast cancer mortality in the USA from 1975 to 2000. The proportion of the total reduction in the rate of death from breast cancer attributed to screening was a median 46%, with adjuvant treatment contributing to the rest.

The three new analyses presented in the 2007 study were undertaken by Frank Lichtenberg of Columbia University in New York and investigated the effect of new drugs and improvements in survival and reduced mortality. Nearly half (44%) of the observed improvement in the 2-year cancer survival rate between 1992 and 2000 at 50 US cancer centres could be attributed to the use of newer cancer drugs. Around one-sixth (14–19%) of the inter-country differences in 5-year cancer survival rates across five major European countries was due to differences in the uptake of newer drugs (post-1985) in each country. Nearly one-third (30%) of the decline in cancer mortality rates seen in 20 countries (including the USA and Europe) from 1995 to 2003 could be attributed to the use of newer drugs. The observed decrease in mortality of 16% would have been only 11% if newer drugs had not been used.

Conclusions

The Karolinska Report and the new extended 2007 study have emphasised that there is a gap in the access to new cancer treatments between countries. All patients should have equal and early access to innovative treatments. Nonetheless, the introduction of innovative treatments must be carefully managed to ensure best practice. Research into patients’ access to therapy is an important component of cancer research.

Further reading

Younger and older women: do their needs differ?

Many similarities exist between younger (40–70 years) and older (70 years and older) women with breast cancer, one of the main similarities being the lack of research and clinical guidelines for these age groups. Younger and older women also have lower survival than women aged 40–70. Treatment of older women must take into account other possible co-existing conditions, and a possible lack of social support. Younger women with breast cancer may be faced with issues of pregnancy and lactation, and career concerns. All women must be offered clear treatment options that are free of age bias. Much more targeted research is needed in these age groups as is the implementation of clear treatment guidelines.

Introduction

There is no single study that addresses the needs of younger and older women with breast cancer and whether or not their needs differ. To answer this question, information must be extracted from the scarce literature incorporating women of these age groups. This article will focus on the similarities between these groups of women rather than on the differences between them.

Younger women are defined as those under age 40 years, while older women are those over 70 years. In many countries women aged 40–70 are included in the treatment guidelines and screening recommendations, although in many countries screening programmes do not include women aged 40. Nonetheless, there is much empirical evidence for women aged 40–69 years and the categorisation into younger and older groups is arbitrary and based on existing guidelines.

Similarities between younger and older women

Women older than 75 years are estimated to comprise only 2.5% of the women enrolled in clinical trials of breast cancer. Consequently, there are few comparative data on tolerability, drug response, treatment efficacy and side effects in this age group. Younger women are also underrepresented in research, although the exact percentage participating in clinical trials is difficult to ascertain as the lower age inclusion limit for many clinical trials remains vague. I conducted a PubMed search of different combinations of key words and found 28 breast cancer studies in the last 10 years that were specifically directed toward younger women. Taking into account the margin of error for this type of search, there would be approximately 50–60 studies on this topic. Some 10,000 articles on breast cancer are published every year, indicating the comparatively low proportion of energy and empirical evidence dedicated to younger women with breast cancer.

Less empirical evidence tends to lead to lack of clarity in the guidelines. Many national guidelines in Europe become vague when considering the younger age spectrum, below 40, and the higher age spectrum, over 70–75. They allow for individualisation of treatment, which means that doctors can decide their own treatment approach, which does not necessarily exclude an age bias. Guidelines are vague, there is no specific treatment recommendation, and treatment standards therefore tend to deteriorate.

In Sweden, compliance with the guidelines in women under 65 is more than 95%, and for women over 65 it is less than 85%. In this respect, there is a similar problem: too little empirical evidence and too few guidelines.

In a study of a Swedish health care region, using the clinical audit database covering 15 years of data and 15,000–16,000 women, we defined two groups of women eligible for adjuvant hormonal treatment, i.e., those with larger tumours, with node metastasis, and hormone-receptor-positive tumours. Over the age spectrum the guidelines were well followed, although guidelines will never be adhered to 100%, due to medical exceptions, etc. It would be expected that use of hormonal treatment in younger women would have been higher than 38–68%, but at the time of the data review adjuvant hormone therapy was not recommended in this age group. Nonetheless, across the age spectrum the adjuvant hormonal treatment guidelines were well followed. For adjuvant chemotherapy, the guidelines were also followed; however, after age 75 their use dropped drastically (Fig. 1).

Considering biological age when making treatment decisions is important. Many women aged 70–75 remain healthy. In Scandinavia a woman who has reached the age of 70 has a mean life expectancy of another 17.5 years. These are many years of healthy, high-quality living for many women. It is a catastrophe to have a large amount of undertreatment in those age groups.
The use of radiotherapy after breast-conserving surgery declines steadily in women over age 70. Elderly women are not as prone to having local recurrence after breast-conserving therapy as younger women. Hence, it is a viable option to withhold radiotherapy in some elderly women who have contraindications for radiotherapy. Nevertheless, radiotherapy is underused in the older age group since there is about a 2% risk per year of local recurrence. The existing quality criteria is 1% per year.

Survival
In a study specifically focusing on survival in the elderly using the health care region database in Sweden, we examined the 5-year breast cancer-related survival taking into consideration the co-morbidities that may lead to earlier mortality (Table 1). The drop in the 5-year survival from 90% for women aged 50–69 and 81% for those 75–79 years may not appear to be a great difference. However, if a new treatment had this type of result on 5-year survival, it would be considered a revolution. It is a very clinically relevant difference. It is unknown whether it is due to undertreatment or to a logical reason that can be influenced.

When we continued this study and looked further at the various stages of cancer and treatments in all types of tumours, clear differences were found between age groups. There was a difference in terms of work-up to diagnosis. Fewer elderly women undergo axillary clearance, they have fewer nodes investigated, and they have more misses on HER2 positivity or hormone receptor status. There is both an indication of underactivity with regard to defining tumour status and with regard to treatment. It is very probable that a substantial part of the difference detected is due to clinical practice and not to biological factors. There is now an ongoing investigation into 5-year survival and clinical practice for the young breast cancer patient group.

In studies of 5-year breast-cancer-specific survival, there is a pattern toward lower survival in the younger and older populations. These findings have been published regularly since the 1980s. Many large cancer registries comprising tens of thousands of women show the same pattern.

We published a paper on the Swedish Cancer Registry in the late 1980s to examine the survival course in biological terms. It seemed that women aged 40–45 had better outcomes and as a result we believed that they had a survival advantage. We speculated that when younger women with hormone-dependent breast cancer began the menopause they experienced a “natural” hormonal treatment that showed a better response to the different treatments. While this might partly explain this finding, now that we have undertaken studies in older and younger women, we might question whether women aged 45–55 experience an advantage, or rather if there is a disadvantage for younger and older women. More needs to be determined on this topic and what can be done to improve this difference.

Cosmetic results
Many studies, such as those by Lesley Fallowfield, have shown that for the great majority of women who are diagnosed with breast cancer, their first concern is the threat of cancer, while the cosmetic results come second. However, given that the best possible cosmetic result is always desired with an operation, all women care about the cosmetic result.

When women are asked, there is no variation in preference for mastectomy or breast-conserving surgery across the age groups. However, when doctors are asked, they tend to believe there is a difference and that older women are concerned less about the cosmetic result than younger women.

Studies by Fallowfield, Hall and other researchers have shown that all women, irrespective of age, want to be offered full information about their different treatment options. Many studies from the UK and some from Sweden also show that women want to be invited to take part in the treatment decision, although not all women want to have an active role in deciding on their treatment. All women want complete, understandable information, and treatment plans must be very clear for the patient. This helps motivate the woman which in turn improves compliance. Over 50% of women express dissatisfaction with their interaction with the health care system. Some of these studies were done 4–5 years ago and such findings may now have improved. There is no evidence that any of these findings vary according to age group. It cannot be assumed that a younger woman wants more information than older women or vice versa.

The doctor is often not in the same age group as the younger or older women. It is well known that doctors, regardless of their experience with breast cancer patients, cannot guess what the patient wants. They must ask the patient. A guess would be influenced by many factors, such as social status, world view, ethical norms and age. Younger women and older women have special needs just by being in these age groups. It must be ensured that medicine is not biased by age.
In summary, the needs of younger and older women with breast cancer are in many aspects similar. Much more targeted research is needed in these age groups as is the implementation of clear guidelines. Quality assurance is critical. Information must be delivered in a professional manner and doctors may require coaching in this area.

Age-biased health care should be avoided as it may disadvantage younger and older women.

**Biological differences**

There are clear biological differences between younger and older women with breast cancer. The reasons for having breast cancer differ depending on the age at which the disease develops. This has implications in prevention strategies, such as in lifestyle factors or for hereditary disease. There is a clear difference between the two age groups.

Hormone sensitivity of the tumour increases with age and can be effectively measured. Breast density occurs more in younger age groups and can reduce the efficacy of mammography. There may be some other as yet unresearched factors that have an impact on disease.

With regard to host defence mechanisms and other biological tumour characteristics, there is comparatively little knowledge and they have not been the focus of active research in terms of an age-related difference. The medical and scientific community will research these different factors out of scientific curiosity. With a little encouragement and stressing age groups, results should become available.

**Specific needs of the elderly**

For the elderly, tolerance to different interventions needs to be investigated and the appropriate duration of chemotherapy in this age group needs to be determined. Further understanding is required about how active breast cancer treatments such as chemotherapy and biological therapies interact with other conditions such as type 2 diabetes, heart failure or lung fibrosis, which tend to occur in the higher age group.

Trials specifically targeted to elderly women are needed. Women over age 70 in many countries account for 20–25% of all breast cancer patients. In many countries these women are not included in the guidelines.

Extending screening is very actively discussed. Some data show that performing one mammography between the age of 70 and 75 would prevent many breast cancer deaths. It would also be an inexpensive approach.

The elderly group must also cope with a failing social network, such as an incapacitated spouse. A social network is important for treatment compliance, especially in the case of more aggressive or active treatment.

**Specific needs of younger women**

In younger women, among the many specific needs are issues pertaining to pregnancy and lactation. This issue has not been well researched, mainly due to the small number of women who have become pregnant and lactated after a breast cancer diagnosis. Coping with family and career life is different from the elderly age group. There appears to be a need for more support in younger women for long-term coping strategies. An older person has more life experience to develop coping strategies for traumatic experiences, such as a breast cancer diagnosis, while a younger person might have more difficulty coping.

It has been shown that more education about risk factors in younger women is needed. A European survey indicated that many young women believed that smoking was the major risk factor for breast cancer, which is not the case. It is a concern that education about risk factors for breast cancer in Europe is lacking for younger women when it is during these younger years that lifestyle choices can prevent breast cancer. On the other hand, older women who were already beyond the most beneficial time in terms of lifestyle changes, were aware of breast cancer risk factors.

Another concern for some younger women is hereditary cancer. There are genetics clinics now available to assess risk. It is an important topic which is quite well covered in many countries and in prospective trials.

The great majority of young women have a good prognosis. Long-term consequences and side effects of treatment are a concern, and education and information about these possibilities are important.

**Conclusions**

Much more active research into younger and older women with breast cancer and their specific needs is required. Treatment needs to be based on clearly structured guidelines. Given the existing knowledge, guidelines could be restructured and evidence could be more effectively accumulated for younger and older women to create separate guidelines pertaining to these age groups.

Systems to implement the guidelines must be established so that the guidelines are followed. As a revolutionary aspect of breast cancer care, there is a growing notion of the importance of guidelines implementation which should make a great difference for many breast cancer patients now and in the future.

It is important to guarantee that best knowledge is practiced at every step. A surgeon from Harvard, Atul Gawande, has published two books in which he stresses that for doctors to provide the best for their patients they need to ensure practice of best knowledge. We need to ensure that all steps are taken to make the prognosis more equal between different age groups, and to make sure that age-biased medicine is not responsible for the differences in prognosis. What we as individuals do today is very important in creating change.

**Further reading**

Specialist breast unit implementation: a case study

The specialist breast unit at Barts Hospital in London is a state-of-the-art, patient-centred unit built following a successful charity fundraising campaign. Primarily serving three socially deprived areas of London, the unit conducts mammography screening and symptomatic care. It contains high-technology imaging equipment and all the facilities required for the workings of the multidisciplinary team. It has waiting rooms with a children’s area, quiet rooms, a patient resource centre, a coffee shop, a boutique and a multimedia lecture theatre. All rooms were designed with attention to the indoor environment and many incorporate artwork commissioned for the project. Funding for the £13.5 million project was acquired by professional fundraisers as well as through networking and support from high-profile individuals. It involved briefings, meetings, speaking engagements and guided tours of the unit, among other activities. The experience from the Barts specialist breast unit can be used to undertake a similar campaign in other European cities.

Introduction

A common sense of frustration can be felt at the apparent inertia in the management of breast cancer, which may be related to the treatment but also to how services are organised. One can feel very helpless in these situations, but as demonstrated below, action can be taken to change this. If enough people join together with the same priorities and targets, changes can be made: I think that is the essence of EUROPA DONNA.

History of St Bartholomew’s Hospital

Barts is the oldest hospital on its original site in the UK and was established by a monk returning from one of the crusades in 1123. The current building where the breast unit is housed is within a Grade 1-listed building designed by James Gibbs 250 years ago. The building underwent some refurbishment just prior to the initiation of the breast unit project.

Barts is in the middle of the historic old city of London and the financial quarter. The breast unit forms the whole West wing. After the merger of Barts with The London Hospital, Barts was threatened with closure in the early 1990s. However, after an independent review in 1998, it was decided that it should persist as a specialist cancer and cardiac unit. Within six years of that decision, the new breast unit was built.

As part of the merger between Barts and The London Hospitals, a large redevelopment initiative and partnership was established. The two new hospitals are currently being rebuilt with an investment of £1.3 billion. It was decided that some advance projects would be undertaken with funding primarily by charity. In the Barts and The London of the future there will be a purpose-built cancer inpatient facility and the breast unit will remain in its current site. It is due for completion in 2014.

The specialist breast unit at Barts

The current Barts specialist breast unit was built with great attention to architectural design. As the project had no financial restrictions, it could use materials and furnishings beyond those that can be afforded in a nationalised health system. With a large budget, a beautiful building and environment, it is unsurprising that the building has won several awards, including the National Award for Patient Environment in 2004 in the UK.

The breast unit has three floors. The ground floor is for reception and waiting. The first floor is where patients are first seen in symptomatic clinics. The second floor holds the diagnostic rooms for breast imaging and cytology. The third floor is for administration offices and also consultant offices.

The ground floor has a very important patient resource centre where patients can sit and acquire information either online or from books and leaflets. The patient support group uses the resource centre to hold its meetings, and some complementary therapies are undertaken there, such as reflexology and massage. There is also a coffee shop, which is nice for patients and their families who are waiting for appointments or investigations. On the wall of the waiting room is a painting that was part of the art commissioned within the overall project (Figs. 1, 2). There is a children’s area. Also on the ground floor there is a boutique for wigs, prostheses and clothes. There is a multimedia lecture theatre where the often large and complex multidisciplinary meetings required for the management of breast cancer can be held. It also serves as an area for teaching and training and has video conferencing facilities.

Our aim was to build a women-centred unit. When asked what they wanted from their breast unit, our patient support group responded that apart from a sense of privacy and secu-
Fig. 1. Waiting room with a children’s area.

Fig. 2. Waiting room.

History of management of breast disease at Barts

The history of management of breast disease at Barts is an important background to the success of the bid to build the specialist breast unit. Barts has a long surgical history.

More recently, in the early 1900s, Sir Geoffrey Keynes was one of the first to advocate breast conservation using radium implants. More recently, Barts was one of the first screening assessment centres in the UK, with initiation of the national screening programme. After the merger between Barts and The London Hospitals, the breast unit at The London Hospital moved to Barts. Now Barts is at the centre of a screening and symptomatic breast care network involving liaison with other hospitals which will result in a more uniform standard of breast cancer care in East London.

With regard to the size of the unit, through the surgical clinics alone there are annually 3,000 symptomatic referrals and about 250 new breast cancer cases. There are 8,500 women on follow-up. Barts Breast Unit is the assessment for the Central and East London Breast Screening Service.

In addition to the outpatient facilities, there is a 14-bed ward for the management of breast cancer, including a full oncoplastic service. All the specialities for the management of breast cancer are on one site.

Case for funding support

The breast group at Barts had an established reputation as one of the better multidisciplinary teams in the UK and was at the forefront of developments in the management of breast cancer. The population served is large and socially deprived, containing two of the top three most socially deprived areas in the UK. The reputation of the unit led to an increase in referrals, but the facilities had not changed since 1945.

As part of the private finance initiative for the redevelopment of Barts and The London Hospitals, charity projects were invited. The Barts specialist breast unit was chosen as the eventual Lord Mayor’s appeal for 2000–2001. An important part of the function of the Lord Mayor, a figure who changes yearly in London, is to raise money for charity. The Lord Mayor chose Barts Cancer Centre, the breast unit, as his appeal in 2001. That was the “kick-start”. Initial funding was obtained from the Bart’s Trustees, which allowed the employment of a large professional fundraising group. The aim was to design a diagnostic unit for the 21st century at a cost of £13.5 million, and the duration of the appeal was to run over four years.

The fundraising team included a Fundraising Committee, the Hospital Trust Director of Capital and Facilities; a project manager; a director of fundraising; specialist fundraisers; and administrative and secretarial support. Many people were involved in order to manage such a large sum of money and to bring the project to fruition.

Much effort went into the literature that was distributed to potential donors. If individuals are being requested to donate large sums of money they must feel that they are dealing with an ultra-professional organisation with a good cause.

The West Wing Project Group, who managed the project, comprised the patient support group, a project manager, an architect, medical and nursing staff, cancer services managers, and somewhat controversially, Vital Arts. This is a group at Barts and The London who supervise art in the environment as an integral part of the healing process. After bidding, the architects were chosen based not on price but on their ability to deliver what was required.

The architectural design had to respect English Heritage restrictions. As we wanted a modern clinical environment, history and modern facilities had to be fused. Putting the patient at the centre, designing it around her was integral to the endeavour. There were no financial constraints.
The arts project arose from a wealthy individual who had already contributed to the project and who wanted to donate more for art. The patients devised the concept for the artist and six artists were commissioned. These were modern artists, such as Cornelia Parker, who is regarded as one of the most significant modern artists in the UK. On the diagnostic floor, one of the artists felt that an entire waiting area could be designed as an art installation.

We were fortunate to be able to engage support from the UK establishment through historical and personal links. For example, a private fundraising dinner and a reception were hosted at Kensington Palace and receptions were held at the Prime Minister’s residence. The Secretary of State for Health toured the unit and used it as a platform to launch health initiatives.

Fundraising strategy

The fundraising strategy involved targeting wealthy individuals, trusts and foundations for larger donations, city companies and institutions, ticketed and cultivation events, and the local community and the public. This strategy resulted in several donations above £1 million and the remainder from £50,000–500,000, for a total of about £8.4 million. Many charities donated.

When involved in this type of project there is a personal “cost” of time committed to briefings, meetings, speaking, guided tours and inevitably asking for large donations.

The experience of working with professional fundraisers was very fulfilling. It was also a unique experience to be able to plan without the worry of financial constraints. The result is the new breast unit, inaugurated by the Duke of Gloucester in 2004. Because it was a charity-derived project and was well run, it finished within budget and ahead of schedule.

Continued fundraising is necessary to develop the equipment, to maintain the fabric of the building, to provide more patient facilities and to support ongoing research.

Learning from the Barts experience

With a unit such as the one at Barts there are value-added aspects to be considered. It is hoped that it will be a beacon to encourage other groups to carry out similar projects. Every city in the UK and in Europe, within reason, should be able to set up an appeal to build a purpose built unit for the management of women with breast cancer.

If asked for advice on how to go about creating a similar breast unit, the first priority would be to have the correct political strategy. There must be a strong case for need (and breast cancer has quite an emotive appeal). There must also be existing expertise with an established foundation and strong leadership. A combination of charity and state funding will achieve the best results most quickly. There needs to be a rapid development of an influential network of friends and supporters. It will take a lot of time and effort but it will be worth it.

Specialist breast unit implementation: a case study Rob Carpenter
Lifestyle factors and breast cancer: nutrition, exercise and CAM

While more evidence-based information on breast cancer risk factors and on complementary therapies is required, some reliable data are available on these issues. In breast cancer prevention, hormone replacement therapy, nutrition, physical activity and alcohol consumption are some of the modifiable risk factors for breast cancer and if appropriately applied could help to reduce the disease incidence. In Europe, a mean of 45% of breast cancer patients use complementary medicine, of which herbs are the most commonly used, despite the scarcity of data on any effects. Other complementary therapies such as acupuncture or progressive muscular relaxation training have been shown to alleviate symptoms of the disease or adverse effects of chemotherapy. Women should lobby for more research into the main complementary therapies so that accurate information will be available to them and to their physicians.

Introduction
There are many unclear messages regarding lifestyle factors and their contribution to breast cancer risk. There is a need for accurate information to empower women to reflect on their lifestyle and make appropriate changes. Complementary medicine (CAM), which is taken in addition to medical therapy, is commonly used by breast cancer patients for wellness and symptom reduction. This article will discuss the modifiable risk factors for breast cancer and the latest evidence for some of the CAM choices that are made in clinical practice.

Influence of lifestyles
A great range of lifestyle factors can contribute to the development of breast cancer. Some known factors for risk of developing breast cancer include: nutrition, age, hormones, physical activity, family history, smoking, alcohol, obesity, chemicals, radiation and pollution. Among these factors are several which cannot be changed, such as pollution in the short term. However, we know that lifestyle choices, such as nutrition and physical activity, play some role in the development of risk in breast cancer. Epidemiological studies show that Asian migrant women who move to a Western country and change their lifestyle habits accordingly, develop breast cancer more commonly than women living in their country of origin. Environment and lifestyle play a role in breast cancer risk.

Known risk factors
Reproductive and hormonal factors
Evidence-based information indicates that one of the key risk factors for the development of breast cancer is the use of hormone replacement therapy. This is the leading lifestyle risk factor for breast cancer. Reproductive and other hormonal factors also play a very important role. Early menarche or having children later in life, and having fewer children are clear risk factors. Thirty years ago, there were 2.5 children per woman; this has fallen to 1.2 and continues to decrease. Late menopause is another risk factor. The use of oral contraceptives is another possible risk factor, though the risk decreases greatly when treatment is discontinued. There is no risk at 10 years after stopping oral contraceptive use.

Nutrition
There is much debate about the role of diet and the appropriate foods to eat for breast health. The literature on well-conducted epidemiological studies is unclear.
Phytooestrogens are oestrogen-like chemicals in plants, the most popular of which are soya products. They are used in symptom management, such as hot flushes, since a diet high in soya was found to decrease hot flushes. However, this remains unclear. Since phytooestrogens are oestrogen based there is a large debate as to whether or not this diet should be used in women.
Whole grains and fibre can slightly decrease the risk of breast cancer, but again the data are inconsistent across the literature. Eating meat, particularly red meat, slightly increases the risk and should probably be limited in the diet. There is no link between breast cancer and consumption of chicken, poultry or dairy products. Dietary fat probably does not play as great a role as once believed. The research is very inconsistent.

Physical activity and exercise
Physical activity and exercise may be associated with decreased breast cancer risk for women of all ages. Potentially, three mechanisms are related to this: i) exercise can increase the age at menarche; ii) exercise can decrease body fat and thus alter body characteristics; and iii) exercise may also decrease the oestrogen levels in the body. By altering hormone levels we can decrease the risk of breast cancer.

Smoking
There have been many messages over the last 10–15 years about stopping smoking due to
the increased risk of breast cancer. While the effect of adult smoking, both active and passive smoking, remains unclear in breast cancer risk, the age at which people start smoking may be the greater risk factor. Heavy smokers who are younger than 20 years of age have a 30–80% increased risk of breast cancer. It is the age of starting smoking rather than smoking per se that may matter. Tobacco smoke contains over 1,000 different types of chemicals that can initiate and promote cancer. When breast fluids of smokers are analysed, they are found to contain chemicals from tobacco smoke.

**Alcohol use**

Having a small glass of wine per day, with a total of five units of wine per week, does not increase risk. One unit is a small glass of wine. In greater quantities, the risk of breast cancer begins to increase. For every extra unit, the risk can increase 6–10%. Studies have reported on the high risk of drinking alcohol at a young age and the risk of chronic alcohol use, i.e., high daily intake. In this case, there is twice the risk of breast cancer for women younger than 35. Some studies have suggested that folic acid (vitamin B) may decrease the risk in women who drink more than one drink per day. This requires further study.

**Obesity**

Obesity is a risk in postmenopausal women. In premenopausal women, obesity actually decreases the risk of breast cancer by about 25%. This would be due to the interference with hormone production. In postmenopausal women with obesity there can be increases in the risk of breast cancer of up to 200%.

**Stages of cancer formation**

Lifestyle factors can contribute to stopping or slowing the stages of cancer formation. Over long periods of time, i.e., decades, a cell mutation can lead to the development of a cancer cell. Lifestyle factors decrease the cells at risk. Thus, from the time of the initial cell mutation, an intervening factor such as childbirth, or diet, could reduce the initial cell mutations such that they do not develop into cancer cells. Childbirth and diet play a key role in this regard.

**Prevention of breast cancer in the EU**

I have calculated the influence of certain lifestyle factors on the burden of breast cancer in Europe (Table 1). There are approximately 250,000 breast cancer patients in Europe every year. If appropriate lifestyle changes were made, there could be 25,000 to 30,000 fewer cases of breast cancer in Europe per year.

<table>
<thead>
<tr>
<th>Risk factor</th>
<th>% contribution</th>
<th>Cases prevented</th>
</tr>
</thead>
<tbody>
<tr>
<td>Use of HRT</td>
<td>4.7%</td>
<td>12,690</td>
</tr>
<tr>
<td>Obesity</td>
<td>4%</td>
<td>10,800</td>
</tr>
<tr>
<td>Activity</td>
<td>3.2%</td>
<td>8,640</td>
</tr>
<tr>
<td>Alcohol, smoking</td>
<td>Some ↑</td>
<td>?</td>
</tr>
<tr>
<td>Breast feeding</td>
<td>Some small ↓</td>
<td>?</td>
</tr>
</tbody>
</table>

**Maintaining well-being in women living with breast cancer**

In addition to the prevention of breast cancer, lifestyle changes also help to prevent secondary cancer in patients with breast cancer. In patients with breast cancer, nutrition and exercise are important. Exercise is a common complementary therapy as well as a therapeutic approach in the management of lymphoedema. It has been shown that five minutes of exercise in the affected arm and arm massage can improve the lymphoedema by about 30%. Mild exercise can be used in the management of cancer-related fatigue, which is another major concern. Improving well-being is the aim of complementary therapies.

**Use of CAM**

In 2006, we presented the results from a European survey of 282 breast cancer patients and their use of CAM. The mean use was 45%, with the lowest use in Greece (≈16%) and the highest in Italy (≈73%), indicating that nearly half the patients were using CAM. However, when the researchers were preparing to collect the data, many of the patients wanted to know if the information would be given to their doctor before they would agree to participate. This shows that many women are afraid to communicate this information to their physicians.

The most common complementary therapy used was herbal medicine. We conducted a larger study on use of herbs in more than 1,000 patients and found about 350 different types of herbs used in the sample. The most worrying fact was that most of the patients did not know the name(s) of the herb(s) they were taking. Spiritual healing, relaxation, medicinal teas and homeopathy were some of the other more common complementary therapies used in this survey. In total, 28 different types of complementary therapies were used at the time we conducted the survey.

When asked why they used complementary therapies, many of the patients stated that they wanted to increase their ability to fight the disease. They therefore sought additional treatment to cure their breast cancer. When later we examined how well the original reason for using complementary therapy matched with the outcomes, we found that very few patients experienced an impact on survival, or cancer cure; however, the rates of improving emotional well-being, hope, and managing some of the symptoms, were much higher at the end of this process. Hence, it is evident that complementary therapies are not about treating the cancer or curing the disease, but more about improving the cancer journey. Regarding sources of information about complementary therapies, the vast majority of respondents received information from friends. The second most common source was the media. This is a major concern because it highlights the fact that patients do not receive accurate information. The information is anecdotal and not evidence based, and may be sensationalised by the media, who do not necessarily provide a balanced view of results. Disappointingly few patients (18%) spoke to their doctors about the use of complementary therapies, and even fewer discussed them with their specialist nurses (5%).

**Evidence for CAM: symptom management**

While evidence for CAM is scarce, it is increasing and improving. Complementary therapies are the second largest
business in Europe after mobile phones, with billions of euros being spent every year. Therapies must be used to treat conditions or symptoms for which good evidence exists.

We conducted a randomised trial on the effect of acupressure in chemotherapy-related nausea and vomiting in breast cancer patients. Acupressure involves bands worn on the arm that press particular points. It is very simple and inexpensive (about €3.50 per pair) and can be worn during chemotherapy. We looked at the experience of nausea and vomiting across the last five days of chemotherapy and found significant differences between those with the wrist bands and those without. The use of medications (anti-emetics) was also lower in those with wrist bands.

In another study we examined the effects of progressive muscle relaxation training on chemotherapy-related nausea and vomiting. It was the largest randomised trial of its kind and included 71 patients. Over the seven days, and particularly the first days following chemotherapy, there were significant differences between the group receiving relaxation therapy and that receiving only antiemetics. At day 1, the daily average duration of vomiting in the group who underwent relaxation therapy was about 8 hours compared with 40 minutes in the group receiving only antiemetics, which is a highly significant difference.

We recently conducted a feasibility study to determine the effects of acupuncture on cancer-related fatigue in 47 patients. Fatigue is a very difficult to manage symptom in clinical practice. Patients were randomised to receive acupuncture or sham-acupuncture, a control technique in which a less effective treatment is given. It was found that by the end of the three-week period, the intervention group showed considerable improvement (36%) in the levels of fatigue. However, when the patients returned for the one-month follow-up, it was observed that the improvement had begun to decline significantly to about 22%, which means that the patients were undertreated. With funding from Breakthrough Breast Cancer, we are conducting the largest complementary therapy study in the UK to date. It is a three-year, multicenter trial to examine the treatment used in the feasibility trial and aims to improve some aspects of the first study. In three years we will be able to demonstrate whether or not this technique can be used to manage fatigue appropriately.

Herbs
The use of herbs is a very hotly debated topic. It is known that some herbs can cause side effects. For instance, when certain herbs are co-administered with docetaxel and other taxels they decrease the effectiveness of chemotherapy. There are many in vitro, laboratory studies using herbs, but very few human studies. The only data available show that some herbs have biological activity, which is to be expected since some of the medicines currently in use are derived from plants. Ginseng has been shown in vitro to have potent tumour therapeutic activity and to improve the cell immune system. Some other Chinese herbs such as Gastroderma lucidum have been shown to have antitumour activity against breast and prostate cells in the laboratory. Many women use various herbs to manage hot flushes, especially after tamoxifen treatment. The most popular is red clover, although all the systematic reviews on this herb show that it has no effect on improving hot flushes. Systematic reviews indicate that black cohosh does show some effect on improving hot flushes; however, black cohosh also has oestrogenic effects which may be contraindicated in breast cancer. St John’s wort, another popular herb, has been shown to be equally effective as antidepressants in many trials for mild depression. Only one trial shows that ginger can also be used during chemotherapy to decrease nausea and vomiting.

Other CAM therapies
Much new research is being released on CAM therapies. Mindfulness-based stress reduction programmes have been associated with improvements in quality of life, stress and sleep quality. Several studies show that Tai Chi Chuan, the ancient Chinese exercise technique, may improve functional capacity in breast cancer patients. Arm exercise can improve lymphoedema. Four studies are examining the effects of either hypnosis or acupuncture on improving hot flushes in cancer patients who are receiving tamoxifen or aromatase inhibitors.

Future directions
Lifestyle changes can definitely prevent the development of breast cancer and can improve survivorship in patients with breast cancer. Culturally appropriate health promotion messages need to be provided. One of the current mistakes has been to focus on aspects that are difficult to change. In the UK, for example, women are told that they need to have children earlier in life. However, women are in the workforce and will not leave their career to have a child in order to slightly reduce their risk of breast cancer. We need to find a culturally appropriate message for women in order for the messages to have an impact.

We know that women with breast cancer do use and can benefit from exercise and complementary therapies, but there is a large range of these therapies available. In an Internet count study I conducted a few years ago, about 370 different complementary therapies were offered. It will be impossible to gain evidence for all of these therapies. We must therefore identify the most used therapies and team up and advocate research and funding for these therapies.

Steps are now being taken to begin testing the effects of some complementary therapies. The evidence in CAM is minimal but increasing and it is recognised that investment is needed in this area. Communication about CAM between patients and health professionals needs to improve. We need accurate information for women to make the best choices for themselves. Health care professionals also need accurate evidence-based information to be able to recommend for or against therapies. At the end of the day, it is the woman’s decision and it is the health professional’s duty to support her in her decision. To do this, accurate information is required; however, for most complementary therapies it is not yet available.

Further reading
EUROPA DONNA lobbying activities: 2001-2007

Susan Knox  
Executive Director, EUROPA DONNA

The European Parliamentary Group on Breast Cancer (EPG-BC) was established in 2001 and has been very active since then in presenting breast cancer issues at the European Parliament. EUROPA DONNA provides the Secretariat for the EPG-BC, which involves liaising with the group, suggesting areas for action, participating in many of its activities and managing the group website, www.epgbc.org. Some joint EUROPA DONNA-EPGBC activities have included receptions and exhibitions at the European Parliament, the first of which took place in 2002. These events help to raise awareness about all the aspects of breast cancer services and screening. EPGBC Expert Meetings have also been held at the European Parliament to ensure that parliamentarians are informed about various breast cancer issues, such as specialist breast units, screening and the potential to use EU Structural Funds for screening programmes. This information is provided so that MEPs can apply it at a national level and help achieve ED’s goal of best practice across Europe.

EUROPA DONNA is a collaborating partner in the European Cancer Network (ECN) and with the European Commission. The European Union, via the European Commission, supports ED’s annual Advocacy Training Course. This course teaches advocates about the European Guidelines for Quality Assurance in Breast Cancer Screening and Diagnosis, the fourth edition of which was published by the European Commission in 2006, so that they can return to their countries and share best practice at the country level. ED also participated in the development of these EU guidelines through the European Commission’s Guideline Working Group.

EUROPA DONNA has also been involved in supporting the establishment of national all-party parliamentary breast cancer groups. At the European level, ED has held three joint meetings where existing national all-party groups shared their experience with parliamentarians from countries without all-party groups in order to encourage establishing such groups.

At a European level the EPGBC has been very successful in furthering breast cancer issues, increasing awareness of them, and promoting the creation of the EU guidelines on breast cancer and having them passed at the European level. The current challenge is to have these guidelines passed by national parliaments. ED produces a variety of publicity materials to support this, including the annual Lobbying Update covering ED’s advocacy activities at the European Parliament and elsewhere; a brochure describing the EPGBC and its activities in the Parliament to encourage other parliamentarians to become involved; and the creation and management of the EPGBC website.

It can be difficult to quantify and evaluate the results of lobbying activities. However, there is no question that ED, in conjunction with numerous partners, has managed to achieve results that have led to better services for women with breast cancer. Advocacy groups for other disease categories such as cervical and colorectal cancer have also approached EUROPA DONNA for guidance.

Following ED’s first reception at the European Parliament, the European Commission established the European Patient Forum and the European Health Forum as it recognised that patient involvement was essential at the European level. Because of the impetus gained by the EPGBC, in 2003 and 2006 two European Parliament Resolutions on Breast Cancer were adopted by the Parliament and have been very important in ED’s lobbying campaign. A revised version of the European Cancer Code also now includes mammography screening.

ED Executive Director and European Board members participated in the EU Guidelines Working Committee and contributed, among other chapters, to the chapter on specialist breast units which was included in the fourth edition of the EU guidelines. At the European Parliament ED
and the EPGBC have held workshops dedicated to creating guidelines for breast care nursing in order to improve the understanding of a discipline that is not well known in all European countries.

Today’s priority is to ensure that these EU guidelines are implemented to achieve best practice. This is a challenge that ED must face with its lobbying campaigns, educational programmes and awareness activities. As the EU guidelines document is over 400 pages in length, and is complicated to understand, EUROPA DONNA recently published *A Short Guide to the European Guidelines for Quality Assurance in Breast Cancer Screening and Diagnosis*. The “Short Guide” summarises the full guidelines document, which was mainly aimed at specialists and physicians, and provides a version of the guidelines that advocates can use to demand better services in all countries. It will be an extremely important booklet in ED’s lobbying efforts. It will especially help advocates in their important task of making the original document comprehensible for parliamentarians and their constituents, so that breast services will be implemented at a national level.

At the EUROPA DONNA Information Day at the European Parliament on 17 October 2007 (Fig. 1), the “Short Guide” was distributed for the first time. A recent EPGBC meeting was dedicated to establishing an accreditation system for screening and treatment of breast cancer. There will also be movement toward national accreditation.

EUROPA DONNA’s strength has always been its European scope, strategy and goals, together with its extensive network of survivors and individuals working at the national level: the ED Fora. This enables the Coalition to have a large impact on European institutions and national health services. In 2008 the focus will be to use the “Short Guide” for lobbying, education and information programmes. It will be used at a European level through the EPGBC and the European Patient Forum, and will be distributed at the 6th European Breast Cancer Conference (EBCC-6) in Berlin. Its use will be discussed in the Advocacy Training Course and at other conferences and events. It will be distributed through mailings, the ED website and will be provided to the media. This can also be done at the national level to ensure progress on best practice. It provides the EU guidelines in one booklet, giving ED one voice, one strategy and one set of goals. There is now one set of guidelines in a manageable format that can be used by advocates successfully across Europe.

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**Ensuring progress on best practice: EUROPA DONNA Belgium**

Mariane De Vriendt  
*EUROPA DONNA National Representative, Belgium*

In 2004 Belgian MP Magda de Meyer and five other Belgian parliamentarians introduced a Proposal for a Resolution on the implementation of breast units. A Belgian Interparliamentary Group on Breast Cancer was also formed at the initiative of Ms de Meyer and Senator François Roelants du Vivier. The official launch occurred in the Belgian Senate, and included patients, EUROPA DONNA members, scientists and politicians. The breast cancer interparliamentary group is the largest and most active group of its kind in Belgium with 54 members, including men.

In 2005 a bill was tabled on breast units. In March 2006, there was a discussion in the Senate Health Commission with contributions from specialists, including ED members. The minister reacted firmly and promised to find a faster method than a bill to have breast clinics legislated for.

In May 2006, there was a session on plastic surgery in the Senate Health Commission. Also in May there was a discussion on the financing of trastuzumab (Herceptin®)

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![Fig. 2. The Belgian interparliamentary group meeting at the Belgian Senate in October 2006.](image)
Panel on guideline implementation, all-party parliamentary groups and national lobbying activities

Ensuring progress on best practice: EUROPA DONNA France

Nicole Zernik
EUROPA DONNA National Representative, France, and EUROPA DONNA Vice-President

ED France was a partner and one of the players in the implementation of the French Cancer Plan in 2003. The Cancer Plan has helped to provide more human and financial resources; to establish a cancer group at the National Assembly; to establish the National Cancer Institute; and to set up “Cancéropôles” (i.e., very large units) dedicated to research. The Cancer Plan also resulted in a large effort to increase quality of care, through the extension of mammography screening programmes across France to include women aged 50–74 years in 2003. The multidisciplinary approach is now used in every centre, and accreditation of hospitals is in progress.

France does not have an interparliamentary breast cancer group as in some countries. Yet, even without it, the results in France are among the best, similar to those in Sweden. ED France contributes to this through several initiatives such as CEPO (described below), organising meetings at the Senate and targeted mailings to senators.

CEPO is the Committee for Exchanges and Projects in Oncology and involves key opinion leaders, some politicians and ED. It was created in 2004 by industry and holds about four meetings per year in the National Assembly with approximately 80 multidisciplinary participants. Many MPs are members of this group and attend the session because they are aware of its importance and want to show their interest. Attendees include health care professionals, politicians, the Health Ministry, National Institute of Cancer representatives, nurses, pharmacists and national industrial partners. CEPO has three major working projects, in screening, treatment and research. The screening project aims to improve results in the national screening campaign, and to encourage authorities to include digital mammography in the screening programme. CEPO also aims to educate GPs and gynecologists about screening. Another CEPO working project is dedicated to access to quality treatment. Regarding research, only about 5% of patients in France participate in clinical trials. ED France is working to increase this participation. In October 2007, the health minister promised 50 journalists at a meeting at the Ministry of Health that digital mammography would be included in the screening programme before the end of the year.

Every year in June ED France holds a full-day meeting at the Senate. It is dedicated to a different topic every year and there are some 300 participants, including politicians and senators. Attendees have the opportunity to listen to key opinion leaders and to patients’ testimonies, and to meet members of the press. In June 2007 the conference was dedicated to the theme “Another life ahead of us” and was very successful.

ED France also reaches out to politicians through mailings, particularly following elections. They write to female senators to congratulate them and remind them of ED’s mission and how it is important for them, as women, to join the group.

The French Forum’s actions have led to an improvement in access to treatment and in quality of life for patients. There is also now better adherence to the screening programme. Many women still go for screening without being included in the screening programme, since there are two parallel methods of participating. ED France encourages women to participate in the organised screening programme, which has double-reading and follows various specifications. We are lobbying to reduce the time between diagnosis and treatment, and for better information to improve compliance. We also encourage better communication between doctors and their patients, and have improved the access to psycho-social assistance in all hospitals.

Much can be achieved though all-party parliamentary breast cancer groups, but much can also be achieved through motivation and key opinion leaders.

ED France will continue to work toward European guidelines implementation in France.
Slovenia is in the process of implementing a population-based, quality-assured breast cancer screening programme which will follow the recommendations of the European guidelines. The programme is called “Dora”, which is a woman’s name and represents the compilation of two Slovenian words meaning breast and cancer.

Slovenia has 2 million inhabitants, just over 1 million women, one-quarter of whom are aged 50–69 years. Breast cancer ranks first in terms of cancer-related morbidity and mortality. Organised breast cancer screening according to European guidelines is due to start in December 2007.

As in all developed countries, including Slovenia, breast cancer incidence is increasing and almost 1,100 women are diagnosed with breast cancer in Slovenia every year. According to the Slovenian Cancer Registry data, 372 women died of breast cancer in 2003. Unfortunately, despite widespread opportunistic screening, breast cancer awareness and improved diagnostic procedures, the percentage of localised disease has increased in the last 20 years. However, breast cancer survival is improving. For age-specific mortality rates, an increase is apparent in only the youngest age group (30–49 years). This group of women is the most aware of breast cancer.

Slovenia does not yet have organised population-based breast cancer screening. Women may undergo mammography in a diagnostic setting, but opportunistic screening without quality assurance and control is not giving satisfactory results.

Organised breast cancer screening according to the EU guidelines is an effective method for early breast cancer detection and breast cancer mortality reduction.

Women who participate in opportunistic screening are young, intervals between screenings are too short, and a clinical examination is still part of the screening exam.

Slovenia is now organising screening according to the EU guidelines (Fig. 3). There will be two stationary units and five or six mobile units. The main obstacle is the separation of diagnostic and screening services in the current decentralised system. ED Slovenia is actively involved in the organisation of the Dora screening programme. They are working to increase breast cancer awareness by holding lectures, publishing news and organising several events. Finally, they are also closely co-operating with the Ministry of Health, experts in the field and other non-government organisations.

**Fig. 3.** Breast cancer incidence in Slovenia and coverage of the population-based screening programme.
Advocates were given the opportunity to discuss concrete ways to apply the information provided during the conference, and to express their frustrations and share their achievements with other advocates. Three concurrent workshops chaired by current or former EUROPA DONNA Board Members were dedicated to employment issues, advocacy tools for implementing the guidelines, and age discrimination in screening and trials. At the same time, a networking meeting was held for young women with breast cancer.

**Employment issues and breast cancer**

The workshop chaired by EUROPA DONNA Board Member Adriana Bonifacino and reported on by Board Member Sanja Rozman, emphasised the need to identify the different working situations of breast cancer survivors in different countries. Adriana Bonifacino presented data on the return to work of cancer survivors. Studies show that about 20% of women do not go back to work, and 75% change employment (reduced working hours, easier job) due to the consequences of the disease. She reported on a survey in Italy on employment issues after breast cancer which involved the distribution of 5,000 questionnaires. Data interpretation has not yet been conducted. There is “anecdotal evidence” on dismissal of cancer survivors in Greece. There was some breakthrough research in the UK. In Sweden it is against the law to discriminate against a worker due to a disability. In Cyprus most women return to work after 18 months of sick leave, but they cannot choose to do another job. In Germany the Women’s Health Network has conducted research on the poverty of women with breast cancer. In the Netherlands there is a rehabilitation programme that assists women in returning to work.

The main theme of the debate was the recognition by advocates that for most cancer survivors, work is a financial as well as an emotional necessity. They keep working not only for the financial benefit, but also for the accompanying self-esteem and social support. Most countries have laws against discrimination of survivors, but in practice some legislation can be bypassed by employers. The flexibility of working conditions is a great advantage in returning to work (reduced working hours, easier job). The women from Eastern European countries may have more physically demanding jobs and are forced to keep working in spite of disabilities due to poverty. In Western European countries, the survivors regard the right to keep working as a privilege rather than an obligation.

It was discussed that it could be very important for ED as a pan-European organisation to research these differences, revealing the differences among countries in workers’ protection from discrimination as well as workers’ safety in regards to environmental and physical strains at work that can influence a survivor’s health.

**Advocacy tools for implementing the guidelines**

More than 40 advocates attended the workshop on EU guidelines implementation, chaired by EUROPA DONNA President Ingrid Kössler and Past-President Stella Kyriakides. Advocates spoke of the obstacles their countries face in implementing population-based screening, including decentralised health systems, lack of cooperation between hospitals, competition between hospitals and surgeons, inability to meet the minimum number of breast surgeries per surgeon, and long waiting lists for mammography. Ingrid Kössler urged the participants to have patience and stay motivated, since the high-quality screening programme existing in Sweden took at least 30 years of lobbying to establish. Advocates from countries with national screening programmes expressed concern about how to increase the number of women who participate in screening.

Among the lobbying strategies advocates suggested to improve awareness of the need for screening programmes and high-quality breast care were the following:

- Lobbying doctors to get them on board and involve them as scientific advisors
- Lobbying politicians and Ministers of Health
- Increasing media attention to breast cancer by involv-
EUROPA DONNA workshops

Age discrimination in screening and trials

The workshop chaired and reported on by EUROPA DONNA Board Member Astrid Scharpantgen revealed that many countries have implemented, or are working to implement, screening programmes for women aged 50–69 years and that only a few have contemplated extending the age threshold.

In the UK, women with a family history of breast cancer are included in mammography and MRI screening from age 40 years. A survey of women aged 70 and over who are required in the UK to self-refer found that 88% of the women surveyed had not discussed mammography with their doctor. It was suggested that GPs and women over 70 need reminders in this regard.

In Sweden, it has been found that once a screening programme is in place, it is very cost-effective to perform one mammogram in women between the ages of 70 and 75. At lower ages, increased intervals of screening are needed. The lower age limit for screening is being reduced to 40 years.

In the Netherlands there is an ongoing court case in which three women aged 75 and over are demanding that screening be available on a voluntary basis for women aged 70 and older. For younger women at risk there are special programmes in some hospitals, but this aspect is still under discussion. A course for GPs to help identify risks has been developed.

There was a brief discussion on the potential of a European decision on the implications of having screening only available for certain age groups; however, it was acknowledged that the EU cannot intervene in national health policy. It was agreed that the availability of figures for each country would be a useful lobbying tool.

Networking meeting for young women

A networking meeting for young women with breast cancer was led by the group co-ordinator Karen Benn. EUROPA DONNA formed a Young Women’s Network, which stays in touch mostly via email, after an ED Working Group for Young Women was held in Milan in June 2005. In 2007, ED provided bursaries for five young women to attend its biannual Pan-European conference and a further two bursaries for young women to attend EBCC-6 in April 2008. In addition, beginning in 2008, the EBCC-6 Organising Committee decided to award five “European Donna Fellowship Grants” for five young women to attend EBCC. At each ED conference there is a networking meeting held for young women. There is information specific to young women with breast cancer on the ED website and a page in the ED Passport is also specifically aimed at young women.

The Amsterdam networking meeting provided young women attending the conference (for these purposes ED defines “young” women as those diagnosed with breast cancer under age 40) with a chance to meet, network with each other and share experiences and strategies. The networking meeting was very well attended, with 21 delegates from countries such as Israel, Cyprus, Holland, Estonia, Greece, Bulgaria, Romania, Slovenia, Switzerland, Georgia, Lithuania, Belgium, Luxembourg and Ireland present. The vast majority of these young women had not attended any previous ED networking events for young women, so the attendees started by introducing themselves and sharing their personal stories.

In the open discussion, the women suggested ways of networking with other young women in their countries to share issues that are common specifically to younger
women, such as fertility, pregnancy during breast cancer and the care of young children, and issues that are common to all women with breast cancer but have potentially a greater effect on younger women such as work-related issues, financial issues and so on. The women discussed how workplace concerns included not only potentially losing a job but also becoming stuck in current employment or not being able to take sufficient time off work when unwell. They discussed how legislation on workplace discrimination could protect women with breast cancer. They also discussed how scientific and sociological research on issues specific to young women with breast cancer was very important. They talked about tactics that have been successful in their countries in terms of networking with other young women, such as the Amazons website in the Netherlands, and other ways of reaching out to young women, such as the booklet recently produced by ED Ireland entitled *Breast Cancer and Fertility*, which was distributed at the conference.

At the end of the meeting, the women agreed to be added to the existing mailing list of the ED Young Women’s Network. Including these women, ED’s Young Women’s Network now has around 30 members.

All ED Fora are asked to encourage any young women who are interested in getting in touch with young women with breast cancer in other European countries to contact Karen Benn (karen.benn@europadonna.org), the ED Young Women’s Network Co-ordinator, who will put them in touch with the group.

### Workshop highlights: how to ensure progress

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<tr>
<th>Topic</th>
<th>Details</th>
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<tr>
<td>Research differences between countries in the working situation for women during and after breast cancer</td>
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<td>Determine whether or not breast cancer survivors are given protection from discrimination in the workplace, and if existing laws are enforced</td>
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<td>Lobby for legislation against workplace discrimination</td>
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<td>Help protect a woman’s right to work and encourage flexibility of working conditions for women during and after breast cancer treatment</td>
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<td>Encourage the understanding that work is a financial necessity as well as a source of social support and self-esteem in breast cancer survivors</td>
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<td>Ensure that workers are guaranteed safety in regards to environmental and physical strain that can adversely affect a survivor’s health</td>
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<td>Lobby doctors and health professionals to involve them in initiatives promoting the implementation of the EU guidelines</td>
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<td>Increase media attention to breast cancer by involving prominent women, clinicians and celebrities</td>
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<td>Disseminate accurate statistics on breast cancer to raise awareness</td>
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<td>Obtain data on the age groups covered in national screening programmes throughout Europe as a tool for lobbying</td>
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<td>In countries with established screening programmes, lobby to extend the age for screening to include younger and older women</td>
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<td>Promote scientific and sociological research on issues specific to young women with breast cancer</td>
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<td>Emphasise the need to use the European guidelines to roll out mammography screening programmes</td>
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<tr>
<td>Lobby to accomplish EUROPA DONNA’s mission to mobilise European women in pressing for improved breast cancer education, appropriate screening, optimal treatment and care</td>
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Two EUROPA DONNA surveys, one on genetic testing for hereditary breast cancer and another on tissue banking, were completed by ED Fora in 2006 and 2007, respectively.

**Genetic testing for hereditary breast cancer**

The survey was compiled to establish whether or not genetic testing for hereditary breast cancer is available in each country, what standards are in place, and what is the quality of testing as well as the context in which it is available. Based on the responses received from 22 countries, 19 had genetic testing available. Sixteen countries said that there are set conditions which qualify women for genetic testing. Twelve reported that counselling was always given prior to testing; the remaining seven said that it is sometimes given. Clinical guidelines for this type of genetic testing were reported to be available in 14 of the 19 countries and just over half of the countries reported that they knew of clinical trials in the area of genetic testing for hereditary breast cancer.

Regarding funding, 13 of the countries reported that the costs of testing were covered 100% by their health services, while 10 countries reported that private companies also provide genetic testing for breast cancer. Life and health insurance companies do not or cannot ask clients or potential clients about the results of genetic tests, but they can ask about “known familial disease”. Such questions are banned, for the time being, in a few countries such as France, Israel and the UK.

More than half of the countries reported that it took from 2 weeks to 3 months to obtain results of a single-site mutation test, with three countries (Cyprus, Hungary and Poland) saying less than 2 weeks. Norway and Slovenia reported 3–6 months for this test with Belgium and Turkey reporting that it usually takes more than 6 months. For the results of tests for mutation searching or full sequencing, Croatia, Finland, Germany, Greece, Hungary, Israel and Poland all said 6 weeks to 3 months; Cyprus, Ireland and Norway reported 3–6 months; Belgium, Netherlands, Slovenia, Sweden and the UK reported 6 months to 1 year and three countries, Italy, Turkey and Austria, said it can take more than one year (Fig. 1).

These results led to the conclusion that the vast majority of ED member countries who responded to the survey have genetic testing for hereditary breast cancer available to them. However, standards and timings of the results vary greatly from country to country, and there is no European standardisation.

Results from this survey were also reported in the ED newsletter in 2007 and are available on www.europadonna.org.

**Tissue banking**

Preliminary results are available for the Tissue Banking Survey, to which 18 countries responded. Of these countries, 13 reported that they are aware of tissue banks that collect breast cancer tissue for research. Nine of the 13 said that national legislation exists to cover tissue banking practices. In eight countries where legislation exists a national regulatory body produces guidelines governing tissue banking.

Regarding consent, almost half of the countries used written consent forms for tissue collection, while the other half did not. In some countries there is a system of “presumed consent”.

The vast majority of respondents, 11 countries, said that ED should try to be involved in the governance of tissue banks and in research projects using breast cancer tissue. Only two countries reported that patients’ groups are currently involved in the process of drawing up guidelines or legislation, while three countries reported that patient groups, including ED, are involved as members of Boards and Committees overseeing the management of biological materials, including collection and storage.

It was concluded that, similar to genetic testing, there are no standard protocols for tissue banking across Europe. Standards greatly vary and many countries do not yet have legislation specifically covering tissue banks.
At EUROPA DONNA’s 8th Pan-European Conference advocates were able to become reacquainted, meet new members and share their experiences at various gatherings over the conference weekend. A welcome cocktail reception hosted by the Dutch Forum featured a folk dancing show and was followed by a dinner. The Saturday conference programme was made complete by a boat tour of the canals of Amsterdam and a dinner by the waterfront.

European Breast Cancer Advocacy

Ensuring Progress on Best Practice
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EUROPA DONNA (ED), 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. ED represents the interests of European women regarding breast cancer to local and national authorities as well as to institutions of the EU.