The 11th EUROPA DONNA Pan-European Conference brought together more than 250 breast cancer advocates and specialists from 37 countries in Prague, Czech Republic, on 19 and 20 October to discuss “Ensuring Quality Services and Equal Access” to breast cancer services. In keeping with this theme, the keynote speaker Krzysztof Maruszewski, Director of the European Commission Institute for Health and Consumer Protection, Joint Research Centre (JRC) in Ispra, Italy, assured advocates that the JRC Breast Cancer Initiative is striving to create a performance-based European quality assurance scheme and accreditation of breast cancer services. This is a key advocacy priority for the Coalition and is fundamental to ensuring that women across the continent have access to equal, high-quality breast cancer care, including screening, diagnosis and treatment.

Throughout the two-day conference, invited experts discussed additional areas that are essential to breast cancer advocacy today: personalised medicine, advances in treatment, mammography screening programmes, pathology and diagnosis, prevention of breast cancer through healthy lifestyles, and survivorship. Advocates were then able to share experiences and strategies in four workshops on advocacy and survivorship, advocacy for young women, special populations and women with metastatic disease.

The biennial EUROPA DONNA Pan-European Conference is unique in Europe in that it is the only conference dedicated primarily to breast cancer advocates and survivors.
Breast Service Accreditation

In the keynote address, Krzysztof Maruszewski of the European Commission’s Joint Research Centre (JRC) assured advocates that work is underway to create a performance-based EU breast cancer service accreditation scheme within the estimated timeframe of end of 2016. The ensuing pilot programme will be the first trans-European health care project of its kind in the EU. Prof. Maruszewski said that one of the first steps needed to achieve this goal will be to update the current 4th edition of the *European Guidelines for Quality Assurance in Breast Cancer Screening and Diagnosis*. These guidelines are an essential basis for establishing unified standards and quality assurance for breast cancer services.

**ABOUT THE JOINT RESEARCH CENTRE**

Prof. Maruszewski explained that the JRC’s role within the European Commission (EC) is as a non-policy-making directorate general that provides scientific and technical support for the conception, development, implementation and monitoring of EU policies. It is composed of scientists working within the EC to provide sound scientific, technical foundations and to advise on EC policies. With headquarters in Brussels, the JRC has seven institutes located in five EU member states; one of these is the Institute for Health and Consumer Protection (IHCP) in Ispra, Italy.

“Whatever you touch in Europe, from aviation safety, to nuclear safety, to food safety, to public health, you will see differences because the member states are different. If we want to do better we have to harmonise. That is where the Commission normally comes in and that is our expected mandate,” Prof. Maruszewski said.

He added that until recently, there had been little impetus from the member states or the EC to act in the field of public health. However, due in part to the economic crisis, the member states have realised that there is a need for harmonisation in order to cut costs and improve services. In response to this, a new division has been created within the IHCP called the Public Health Policy Support Unit, which in turn covers health care quality, among other areas.

Furthermore, the European Parliament Resolutions on Breast Cancer, the Council Conclusions on reducing the burden of cancer of 2008 and the European Partnership for Action Against Cancer point to “unacceptable differences” between member states and call for evidence-based cancer guidelines and voluntary EU accreditation schemes for cancer screening. Prof. Maruszewski said that all of these provide the legal basis for the provision of equal quality services: “The policymakers are actually saying that it is important, that it is a problem. Let’s do something.” The JRC has therefore received a very strong mandate from the Directorate General for Health and Consumer Services (DG-SANCO) to gather the existing European data on breast cancer services so that better results can be achieved.

**UPDATING OF THE EU GUIDELINES**

Prof. Maruszewski said that the EC has proven its commitment to quality breast cancer care through the creation and publication of the *European Guidelines for Quality Assurance in Breast Cancer Screening and Diagnosis*. “I would like to acknowledge the immense importance and immense quality of the work that has already been done to get us to this point,” he said. “It is a cornerstone on which we have to and want to build in order to be able to move toward the future and get better results.”

The upcoming 5th edition of the EU guidelines will be the backbone for the quality assurance criteria for the breast cancer service scheme. It is to be evidence-based and to cover breast cancer screening and diagnosis. Other high-quality guidelines will be selected as a platform for treatment, rehabilitation and follow-up. Prof. Maruszewski added that for ease of access and updating, the guidelines will be published in an online format. With regard to timing, he said that the majority of the updating work is expected to be done in 2014. Supplements to the 4th edition are being published in 2013.
**Breast Cancer Initiative**

The guidelines update is the first step in the IHCP’s Health Care Quality Breast Cancer Initiative, which aims to provide women with a high degree of assurance in all processes directly concerning them for all stages of breast cancer care. The second step in the Breast Cancer Initiative will be the development of a European Quality Assurance Scheme for Breast Cancer Services within the existing EU framework and using existing accreditation schemes and experience in Europe. Prof. Maruszewski added that the scheme is to have a performance-based approach and be compiled using expert consensus, which will allow for traceability. A sustainable, web-based format for maintaining the guidelines and the quality assurance scheme is to be developed.

Ultimately, a pilot European quality assurance scheme for accreditation is to be set up and will be the first of its kind in the health care field across Europe. This process will create reference documents, best practice guidelines, training documents for auditors and auditees, and is to have a web hub. Once it has proved successful, Prof. Maruszewski said they would like to deploy it in other health care areas.

He added that the scheme is being developed to alleviate the existing inequalities across Europe, while avoiding multiplication of schemes, use of findings that are not evidence-based, and opportunistic programmes. The accreditation scheme is to be the only one available in the EU and is to be sustainable. It is to follow one set of guidelines for screening and diagnosis in Europe, to have controlled criteria for selecting other guidelines for use in other stages (e.g., treatment and follow-up), and it is to put women at the centre of the process.

With regard to timelines for accreditation, Prof. Maruszewski said, “I understand the need for urgency and the need to supply patients with quality assurance as soon as possible. However, the things that will influence the timing are many. For instance, the new guidelines will need to be created and an expert consensus will need to be reached across Europe for all stages. A web-based platform will need to be designed. Plus there will be two key phases to the accreditation scheme: development of the scheme and its deployment by the member states. He added that enough resources have been assigned to reach the end of the first stage by end of 2016.

“That is why it is so critical that there is consensus and agreement from the member states who are going to be paying for it. That is an extremely important point and will influence the timing,” he said, adding that there has been progress and a good response from member states in meetings and visits conducted to date: “The member states have immediately realised that they have something to gain, not only for this project but for other health-related areas as well.”

EUROPA DONNA is a participating member of the JRC meetings and in the breast cancer care scheme.

“The member states have immediately realised that they have something to gain, not only for this project but for other health-related areas as well”
If now we select treatment according to three major families of breast cancer, in the future we have to select treatment according to small molecular alterations that can also be present in a very small fraction of patients."

**Personalised Medicine and Current Research**

Giuseppe Curigliano, Chair of the Early Drug Development for Innovative Therapies Division at the European Institute of Oncology in Milan, Italy, gave an overview of personalised medicine, whereby treatment is selected based on molecular alterations in tumours. In this new era of genetic profiling, where breast cancer is segmented into rare molecular subtypes, he said the most common cancer in women becomes like a rare disease: "If now we select treatment according to three major families of breast cancer, in the future we have to select treatment according to small molecular alterations that can also be present in a very small fraction of patients.” He added that DNA sequencing of tumours enables the identification of the molecular drivers of proliferation that can then be targeted for treatment. Many such drivers are common across the various cancer types and have drugs to target them.

The 2013 St. Gallen expert recommendations provide the state-of-the-art for personalising treatment in women with early breast cancer and describe various subtypes of breast cancer and their recommended treatment options (1) (see Table).

**New Therapy Options And New Pathways**

Prof. Curigliano described some of the various pathways that are being explored for breast cancer treatment, such as the mTOR pathway. The mTOR inhibitor everolimus has been approved in the EU and the USA for the treatment of hormone-receptor-positive, HER2-negative metastatic breast cancer, in combination with the aromatase inhibitor exemestane, in post-menopausal women after recurrence or progression following treatment with a non-steroidal aromatase inhibitor. In the BOLERO-2 study, progression-free survival (PFS) was more than 40% longer with the addition of everolimus, even in women with visceral metastasis (2).

Another pathway is the phosphoinositide 3-kinases (PI3K), which has more than a dozen targeted agents under investigation. Another is the cyclin dependent kinases (CDK) 4 and 6 pathway. There have been promising results for an investigational, oral, selective CDK4-6 pathway inhibitor, palbociclib, combined with letrozole in women with oestrogen-receptor-responsive tumours that progressed on endocrine therapy. In phase II studies, median PFS on the combination was 26.1 months compared with 7.5 months on letrozole alone (3). Phase III studies are ongoing.

**HER2-positive disease**

A number of studies have investigated different durations of treatment, administration routes and combinations of trastuzumab in HER2-positive disease. The HERA trial of adjuvant trastuzumab has recently shown similar findings for 1 year and 2 years of treatment, indicating that 1 year is the standard of care (4). Prof. Curigliano added that beyond 1 year of treatment the risk of cardiac events increases.

A subcutaneous formulation of trastuzumab is approved in the EU and was found to be preferred by 91% of patients over the standard intravenous injection in a trial on patient preferences, the PrefHer trial. The subcutaneous formulation can be delivered in minutes and is administered every 3 weeks (5). Prof. Curigliano added it has also been found to be more effective than the intravenous injection. When administered before surgery (neoadjuvant treatment), the tumour disappeared in 45% of cases compared to 40% in the intravenous group (6).

Prof. Curigliano explained that dual targeting is an approach for the future. The Breast International Group (BIG)’s collaborative APHINITY trial is investigating trastuzumab alone versus trastuzumab and pertuzumab for 1 year (7). Findings from the earlier NeoSphere study indicate that the combination can induce a greater response in the neoadjuvant setting (8). He noted that while pertuzumab is approved by the European Medicines Agency (EMA), it is still unavailable in many countries.
Prof. Curigliano said that the drug of the future is trastuzumab emtansine (T-DM1), which is trastuzumab bound with three types of chemotherapy. The drug is delivered within the tumour cell, which concentrates toxicity inside the tumour cell and reduces medullary side effects. The drug is approved in the USA and the EU for the treatment of adult patients with HER2-positive, unresectable locally advanced or metastatic breast cancer who previously received trastuzumab and a taxane, separately or in combination. Prof. Curigliano added that the economic crisis will likely delay the availability of this drug.

Basal-like disease
One of the main treatment challenges is basal-like disease (ie, triple-negative breast cancer). Prof. Curigliano said that 15% of patients with breast cancer have triple-negative disease and that most of them are younger than 40 years of age. Many of them have the BRCA1 and BRCA2 mutations. While there is no definitive active treatment for this type of breast cancer, studies have examined neoadjuvant chemotherapy with and without the antiangiogenic agent bevacizumab and have found that adding bevacizumab reduced the size of the tumour (9, 10). He noted that the US Food and Drug Administration has stated that if a drug can be shown to increase the percentage of pathological complete response (ie, absence of invasive cancer in the breast), the drug can be eligible for accelerated approval for neoadjuvant treatment of high-risk, early-stage breast cancer (11). “This is a very important step in the drug development process,” Prof. Curigliano said.

In addition, poly (ADP-ribose) polymerase (PARP) inhibitors are in development and have been shown to increase tumour shrinkage in BRCA1/BRCA2 mutation carriers with breast cancer (12).

FROM MOLECULAR SCREENING TO PERSONALISED MEDICINE
Prof. Curigliano explained how the personalised approach was used in the SAFIR-01 trial (13), which selected women with metastatic breast cancer, biopsied the tumour, sequenced the DNA of the tumour and selected treatment according to the molecular alteration. The patients were then assigned to phase I and II studies of an investigational agent. This is the first large-scale study to prospectively test the entire genome from a biopsy of a metastatic lesion, and match any alteration found with a targeted agent. In all, 423 women were accrued, 194 of whom had targetable genomic alterations, and 48 were able to undergo treatment based on the genomic results. Prof. Curigliano added that one of the drawbacks of personalised treatment is the lack of agents available to address each alteration.

BIG is now initiating the AURORA trial with the same study design as the SAFIR-01. An academic trial funded by the Breast Cancer Research Foundation, it is the first attempt to bring personalised medicine into the clinical setting (14). EUROPA DONNA is on the steering committee of this trial.

Prof. Curigliano added that future studies designed to discover targeted agents will need to select patients whose tumours express the molecular alteration. This will require drastic changes to the traditional randomised approach to clinical trials of new treatments and to the drug approval process. Data sharing will also be essential, which can imply data protection issues. Genetic sequencing provides extensive information and may reveal presence of other diseases, which raises the question as to how this information should be managed, the psychological and legal aspects, as well as insurance issues. Prof. Curigliano said, “We need involvement of the stakeholders that are patients, scientists, pharmaceutical companies and regulatory agencies. If we work together we can achieve a programme of personalised medicine.”

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13. ClinicalTrials.gov; NCT01414933.
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Take home messages
- Breast cancer treatment is becoming more targeted to molecular characteristics in tumours and will be more personalised.
- Clinical trials and regulatory processes will need to adapt to this new approach to treatment.
- New treatment pathways are being investigated and some new therapies are available for metastatic disease and triple-negative breast cancers.
- Trastuzumab treatment in the adjuvant setting has a standard treatment duration of 1 year; a new subcutaneous formulation and new combinations are under investigation.
Advances in Breast Cancer Treatment

Peter Dubsky, Associate Professor of Surgery at the Medical University of Vienna, Austria, described the latest in surgical treatment of breast cancer, which must be performed by experienced hands. Surgical techniques taken from plastic surgery can be applied in breast cancer to achieve better aesthetic outcomes than with traditional techniques. He said that in the right patients, oncoplastic surgery can have excellent oncological safety. Surgeons should talk to patients about the possibility of asymmetry, the need for further surgeries and potential morbidity such as delayed wound healing, which, in turn, may delay cancer treatment. In a study performed at the Department of Surgery in Vienna, they found that while the reoperation rates with oncoplastic surgery were low, they were significantly greater than with traditional surgery. Above all, he said, oncoplastic surgery must be performed by breast surgeons with many years of acquired expertise and should be considered in conjunction with the multidisciplinary team.

**AXILLARY LYMPH NODE DISSECTION: STILL NECESSARY?**

Dr. Dubsky also described the greatly debated topic of axillary lymph node dissection (ALND), where fatty tissue in the axilla and the lymph nodes is removed in women with node-positive disease to reduce further spread of metastasis. The gold standard procedure is what is called a level I or II dissection to remove the tissue while sparing some important nerves. Dr. Dubsky said that with careful dissection and by leaving lymph tissue surrounding the axillary vein intact lymphoedema rates are well below 2% in experienced centres.

Sentinel lymph node dissection (SLND), on the other hand, removes the sentinel node while sparing most of the other nodes. However, large prospective studies have shown similar quality of life and lymphoedema rates in the long term for ALND and SLND (1, 2). Other recent prospective trials of ALND versus no dissection with highly selected patient populations have shown similar survival and local disease control without ALND (3, 4). Dr. Dubsky added that retrospective and prospective trials of women with positive sentinel lymph nodes who did not undergo ALND have shown local control and good overall survival.

He concluded that while ALND remains the standard of care for women with a positive sentinel node, there is a population of women in whom the procedure can be waived, such as in the elderly, women with comorbid conditions, those who have already undergone surgery, and in those with several micrometastases.

**WHAT’S NEW IN GENE ASSAYS FOR PROGNOSTIC SIGNATURES**

Breast cancer is a chronic disease, particularly oestrogen-receptor-positive breast cancer, and some studies have shown a 40% reduction in risk of recurrence when an aromatase inhibitor is continued beyond the standard 5-year treatment period. Dr. Dubsky explained that this comes with possible toxicity and added cost, and it would be beneficial to be able to identify women who would benefit from such treatment beforehand. He added that the next step is to apply gene signatures to long-term outcome.

A number of gene assays have been validated in multiple prospective cohorts, such as Oncotype DX®, Prosigna™, Mamprint™, EndoPredict®, MapQuant Dx™ Genomic Grade and Breast Cancer Index™ (BCI). Dr. Dubsky noted that the EndoPredict, the BCI and the ROR score have been effective in identifying women at risk for late metastasis in addition to early recurrence. In Austria, Dr. Dubsky’s group validated the EndoPredict test for late outcomes after year 5. They found that 65% of the women were in the low-risk group, 98% of whom remained free of distant metastasis 10 years after diagnosis (5). He added that studies with ROR and BCI have shown similar findings (6, 7). This may enable the identification of women with a low risk of recurrence who may not need extended adjuvant endocrine therapy.

Dr. Dubsky concluded that several tests, including ROR, BCI, HOXB13:IL17BR ratio index and EndoPredict, are able to provide additional prognostic information about the likelihood of recurrence beyond 5 years, and that predictive data will need to be validated. “There are more than 20,000 women in phase III extended adjuvant endocrine therapy trials. This is truly an undermeasured need. We need to do a much better job in defining who needs extended therapy,” he said.

**References**


**Take home messages**

- Oncoplastic surgery is an option for some women and must be performed by breast surgeons with many years of acquired expertise
- A large number of women with positive sentinel node can avoid undergoing axillary lymph node dissection
- Some of the new gene signature assays have proved effective in identifying low-risk women who may be spared extended endocrine treatment
10 Years of Screening in the Czech Republic

Miroslava Skovajsová, Senior Consultant at the Breast Unit in Prague and President of the Association of Czech Breast Radiologists, presented data from the Czech cancer registry showing a 30% decrease in breast cancer mortality since the 1980s and a dramatic increase in the number of breast cancers detected in their early stages. She explained that in her country, the national breast screening programme screens women aged 45 and older every 2 years in 70 specialist breast units accredited by the Ministry of Health’s Committee for Breast Cancer Screening and the Association of Czech Breast Radiologists.

About the Czech screening programme
- Launched in 2002
- From January 2003 to December 2012, 4,213,986 screening mammographies performed
- 21,315 cases of asymptomatic breast cancer detected, at least 70% in early stages (75.8% in 2012)
- Breast units must perform at least 5000 screening mammograms per year and practice double reading
- Paid for by insurance companies (all Czech women are insured)

The screening programme has led to earlier detection rates. Data from the National Cancer Registry reveal that for the whole population, 31% of breast cancers were stage I in 2000 and 40% in 2009, compared with at least 70% in women who regularly underwent breast cancer screening from 2003 to 2012. Dr. Skovajsová explained that the lower age limit of 45, as opposed to the 50 years stipulated in the European Guidelines for Quality Assurance in Breast Cancer Screening and Diagnosis, was due to the fact that almost the same number of breast cancers were detected in women aged 45-49 (490 cases) as in all women aged 44 and younger (471 cases). She added that in 2010, the upper age limit for screening was dropped because breast cancer continues to be a risk in older women, with, for example, 577 cases in women aged 70-74 years.

Since 2008, the participation rate has been over 50% of women (56.5% in 2012); they are recommended to attend screening by their gynaecologist or general practitioner. The highest participation is among women aged 45-49 at 61%. Dr. Skovajsová added that since only 50% of women in the Czech Republic see a gynaecologist, they plan to set up an invitation system by letter in cooperation with the Ministry of Health.

Dr. Skovajsová also gave a very visual demonstration of the radiologist’s task in detecting tumours on mammography and ultrasound. She added that of the 2000 radiologists in the Czech Republic, about 200 of them are specialised in breast cancer and all radiologists receive training at her breast unit. Every year they hold a 2-day conference to discuss and present some mistakes and failures in breast cancer diagnosis and how to overcome any challenges encountered. In her conclusion she said, “Czech radiologists take care of about 5 million Czech women. My recommendation to you is to join your radiologists because they are the key to decreasing the mortality.”

“Czech radiologists take care of about 5 million Czech women.
My recommendation to you is to join your radiologists because they are the key to decreasing the mortality”

Take home messages
- The Czech national mammography screening programme screens women aged 45 and older every 2 years. There is no upper age limit.
- There has been a 30% decrease in breast cancer mortality since the 1980s
- Many more cases of breast cancer are detected in earlier stages
- The participation rate is 57%
- Advocates should establish contact with radiologists, as they hold one of the keys to diagnosis
Prevention Studies on Breast Cancer: What the Evidence Shows

Isabelle Romieu, Head of the Section of Nutrition and Metabolism at the International Agency for Research on Cancer (IARC), summarised the current evidence for the effect of modifiable lifestyle factors on breast cancer risk. She emphasised the need to maintain a healthy weight, limit alcohol consumption, and practice regular physical activity.

She explained that efforts are being made to categorise the influence of certain risk factors by breast cancer type, such as hormone-receptor-positive or -negative breast cancer. Some of the differences in risk between premenopausal and postmenopausal women are already well established (1).

**Body Weight and Breast Cancer**

While high body mass index (BMI) has been thought to have no association or even a slightly protective effect against breast cancer in premenopausal women, in postmenopausal women it increases the risk. However, Dr. Romieu noted that newer data are indicating that BMI in premenopause does have an influence on breast cancer risk (2). Type of body fat is important: abdominal obesity increases the risk in women of all ages. A recent large study in premenopausal women has shown that increased waist circumference (> 87 cm) more than doubled the risk of oestrogen-receptor-negative breast cancer (2). In postmenopausal breast cancer, overweight (BMI 25-29.9) was associated with a 26% increased risk, while obesity (BMI > 30) was associated with a 40% increased risk (3). She added that another recent study has shown that gaining weight is a risk for post-menopausal breast cancer: an increase of > 7.5 kg between the ages of 45 and 54 approximately doubles the risk (4). Dr. Romieu explained that it is important to maintain an energy balance (i.e., burn the calories consumed) since obesity leads to metabolic changes such as insulin resistance, as well as inflammation, which in turn increase cancer risk.

**Physical Activity and Breast Cancer**

Various prospective studies have shown a protective effect of physical activity in breast cancer. Dr. Romieu noted that the World Health Organization recommends at least 75 minutes of vigorous physical activity or 150 minutes of moderate physical activity per week. Similar to weight, physical activity has an effect on oestrogen levels and other hormone levels and inflammatory markers associated with cancer (5). She added, “I think the message needs to be that a little physical activity every day is beneficial for everybody and not only for cancer, for any chronic disease.”

**Alcohol and Breast Cancer**

Alcohol consumption has been shown to increase the risk of breast cancer by 3-9% for every additional 10-g drink per day. The observation applies to women of all ages and is cumulative throughout a woman’s life. There is no association with type of breast cancer. One study showed a 15% increase in breast cancer risk with 3-6 drinks per week (5-9.9 g/day) (6). Dr. Romieu noted that the risk of binge drinking is of concern, particularly among younger women, since 6 or more drinks in a day increases risk by 33% (6).

Dr. Romieu’s group has recently analysed data from the large European Prospective Investigation into Cancer and Nutrition (EPIC) study and found that the greater the amount of alcohol consumed, the greater the risk of breast cancer (7, 8). She noted that alcohol affects the metabolism of folate and a very recent study has demonstrated that increased folate intake reduced the risk caused by high alcohol intake (9).
Diet

While Dr. Romieu said that very strong epidemiological data on the role of nutrition in breast cancer are needed, enough is known to make recommendations. She is involved in the ongoing update of the European Code Against Cancer, which is to be released in Spring 2014. In an analysis of 334,849 women with breast cancer from the EPIC study, dietary fibre intake and particularly fibre from vegetables was associated with a decreased risk of breast cancer, independently of the women’s menopausal status (10). Another EPIC analysis showed a 40% increased risk of oestrogen-receptor-negative breast cancer among postmenopausal women with the highest levels of carbohydrate intake (11).

Dietary factors and increased risk of breast cancer (12).
- High intake of sugar and fast absorbed carbohydrate (jam, sweet drinks, doughnuts)
- Low intake of fibre, particularly vegetable fibre
- High levels of trans-fatty acids (processed food)
- Low intake of omega-3 fatty acid (fatty fish)
- Low intake of folate (found in green leafy vegetables, lentils, chick peas and fortified cereals)
- Adolescent diet (high meat and fat intake)

For trans-fats, which are found in processed foods, the French arm of the EPIC study showed an almost doubling of risk of breast cancer with the highest amounts of trans-fat intake (13). Omega-3 polyunsaturated fatty acid intake from fish, on the other hand, has been shown to have a protective effect of about 14% (14). Levels of vitamin D are also protective. Results from the French EPIC group indicate a 27% reduced risk among those with the highest exposure (> 27 ng/ml in serum), especially in younger women (15). Dr. Romieu noted that vitamin D is best acquired through sun exposure during the weakest hours of sunlight to avoid other risks such as melanoma.

Breast Cancer Risk Throughout the Life Cycle

Dr. Romieu said that cancer risk is a continuum influenced by behaviour throughout one’s lifetime, including foetal life and particularly in adolescence. In adolescence, high fat or red meat intake prior to menarche is related to premenopausal breast cancer (16). On the contrary, a prudent dietary pattern rich in fruits, vegetables, chicken, fish, low-fat dairy products and fibre reduced the risk of breast cancer by 12%, compared with a 9% increase for a Western diet (rich in red and/or processed meats, refined grains, potatoes, sweets and high-fat dairy) (17).

Dr. Romieu added that the EPIC group will soon be publishing evidence on its Healthy Lifestyle Index of modifiable lifestyle factors. The evidence included in the index indicates that a healthier diet, lower BMI, higher degrees of physical activity, lower alcohol intake and reduced smoking were associated with lower breast cancer rates. The dietary index includes high intake of cereal, folate, ratio of polyunsaturated fat over saturated fat, fatty fish, lower intake of margarine containing saturated fat, and high intake of fruits and vegetables. When these components were combined a 20% reduction in breast cancer risk was found in specific groups.

In her conclusion, Dr. Romieu also added that the same overall lifestyle measures apply to the prevention of secondary breast cancer.

Take home messages for reducing breast cancer risk

- Maintain a healthy weight in adulthood
- Practice regular physical activity
- Limit alcohol consumption
- Limit consumption of energy-dense food; avoid sugary drinks and processed foods
- Eat mostly foods of plant origin (fruits and vegetables, fibre)
- Folate and vitamin D have a potential protective role

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Pathology: Its Growing Importance and What Patients Should Know

Bettina Borisch, Professor at the Institute of Social and Preventive Medicine of the University of Geneva, Switzerland and a EUROPA DONNA Past President, opened her talk with a short story by a woman who was intrigued by the enemy tumour in her breast and needed to “meet” it and confront it with her pathologist. Prof. Borisch then described the fundamental role of the pathologist in breast cancer diagnosis and creating the tumour portrait that enables personalised, targeted treatment.

The pathologist’s main tool is the microscope. In the pathology laboratory, a tumour tissue sample from a biopsy or surgery is fixed in formalin, embedded in paraffin and cut into slices that are 2-4 microns thick. Fresh frozen samples are stored in deep temperature freezers or in liquid nitrogen. The tumour slices are placed on slides, stained with hematoxylin and eosin (H&E) and examined under the microscope. The aim is to determine the tumour portrait, including the tumour appearance, its components, where it spreads, how it grows, what it needs to grow and what proteins and genes are expressed in the tumour cells. Prof. Borisch said that for core biopsy specimens the whole process takes about 6 hours, and for a larger specimen it is one day.

Commercial multigene assays are now available to try to determine prognosis and prediction in breast cancer. Prof. Borisch noted that most of these assays test for a group of 10-20 genes or for expression of certain proteins. The analyses for some of these tests is only performed in a central laboratory, while others are done in different labs. The pathologist must then integrate the conclusions from the assays into the overall pathology report. Prof. Borisch added that in Europe, companies are scrambling to sell these tests and are lobbying governments to pay for them and lobbying patient groups to back them.

She noted that while the pathologist is the custodian of the tumour sample, the sample and the pathology report belong to the patient. Given the latest digital technology and the imaging analysis systems, it is easy to send the samples for a second opinion. Furthermore, tumour samples can be examined years later when there are discoveries of new treatments. She added, “The pathology report – the description of your tumour – is core to understanding your treatment, for you and the doctors dealing with it. The pathology report and the corresponding tissue, like all other documents, belong to you, the patient. You have access at any time to your report.”

European guidelines requirements for information to be included in the pathology report.

- Type of cancer (ductal and grade, lobular)
- Invasive or non-invasive carcinoma or mixed
- Tumour size
- Invasive grade
- Lymphatic or vascular involvement (lymph node status)
- Resection margins (involvement or not of margins; distance in millimetres)
- Hormone receptors (oestrogen, progesterone receptor status)
- HER2 status

Take home messages

- Women should have access to their tumour tissue and the pathology report
- The pathology report should include the tumour features as described in the EU guidelines
- Tissue that has been sent to a pathology laboratory can always be reinvestigated
- A clear pathology diagnosis is required for treatment and for prognostic/predictive information

In conclusion, she said that a woman with breast cancer should have access to her pathology report and have someone explain it to her. She encouraged women to look at their tumour with the pathologist if they feel the need. “You should never accept any treatment without a clear pathological diagnosis and the prognostic and predictive information that comes with it,” she said.
Survivorship: Identifying and Meeting Diverse Needs of Breast Cancer Survivors

Dorothy Goddard, National Clinical Advisor on Breast Cancer for The National Cancer Survivorship Initiative (NCSI) in the United Kingdom, described a system of “self-management” for follow-up care of the growing number of breast cancer survivors.

In the UK in 2012, Dr. Goddard said there were 2 million cancer survivors, about 30% of whom were breast cancer survivors. She added that in 2030, 41% of the estimated 3.4 million survivors in the UK are expected to be breast cancer survivors. Ten-year survival rates in England and Wales have gone from about 40% in the early 1970s to the current-day 85%. This can be attributed to early detection, earlier start of treatment, and availability of more effective treatments.

**Sustaining and Supporting the Increasing Number of Survivors**

Dr. Goddard explained that this growing number of survivors has led to a rethinking of follow-up strategies at hospitals and clinics so that they can dedicate time and resources to treating new cancers or people with cancer recurrence or metastatic disease. She added that for breast cancer most women will live long, healthy lives; however, some survivors may have ongoing physical, psychological or social needs, while others may be living with chronic, incurable cancer. Others may be living with the consequences of the cancer or its treatment, such as menopausal symptoms, osteoporosis, lymphoedema, shoulder problems due to radiotherapy, or fatigue.

In 2010 the UK Department of Health undertook a survey to identify the unmet needs among cancer survivors. It found that conventional face-to-face outpatient follow-up did not meet patients’ needs, nor was it cost-effective. As confirmed in a number of studies, routine follow-up appointments were not found to be effective in detecting recurrence. It was therefore concluded that models of aftercare for the majority of cancer survivors should have much in common with those for other long-term conditions, in addition to providing some specialist cancer-specific services.

The Department of Health, in partnership with a cancer charity and supported by National Health Service (NHS) England, formed the National Cancer Survivorship Initiative, whose aim is “to ensure that those living with and beyond cancer get the care and support they need to lead as healthy and active a life as possible, for as long as possible”. In 2011, the Department of Health published a document, *Improving Outcomes for Cancer*, focusing on survivorship and outcomes.

Dr. Goddard described the five key elements of the NCSI Vision 2012 approach to survivorship.

**Support Through Primary Treatment from the Point of Diagnosis**

Dr. Goddard explained that support begins at the time of diagnosis and must continue throughout the cancer journey. All patients are offered information about cancer and treatment options and are given support in making a treatment decision. They receive support throughout treatment and advice on managing work and finances.

**Promoting Recovery**

All patients must be offered a tailored package of care, including a treatment summary (shared with their family doctor), so that they know all the details of their cancer and their treatment. They should also be given a care plan that is individual to the patient, the type of cancer and stage and what is required for ongoing care. Dr. Goddard said that the holistic needs assessment is a fundamental part of this, wherein all the needs of the patient are considered, such as physical and lifestyle, social, financial, occupational, psychological and spiritual needs.

She explained that for NCSI the survivorship phase begins upon completion of the acute treatment (e.g., after chemotherapy or radiotherapy). At this stage, a holistic needs assessment is conducted using a tool such as the “distress thermometer”, which is a form that the patient fills in to rate her concerns about a number of areas, such as physical, practical, family/relationship, emotional, spiritual/religious and lifestyle or relationship needs. A care plan is created summarising the main concerns, how significant they are and a plan for action. An electronic version of the assessment tool is also provided to women on a tablet for them to answer before they have their first post-treatment mammogram. Further holistic needs assessments may be appropriate at any later points that may require care, such as after complications of treatment or further disease.

The care plan includes advice on recovery from a range of professionals, provided through health and well-being clinics or “moving on” days. These are held several times a year in the form of an interactive symposium where professionals address key areas of concern, such as managing effects of treatment, and exercise and nutrition advice. Women are also able to make contact and network with other survivors.

**Sustaining Recovery**

Supported self-management is the new care model that has replaced routine clinical follow-up. Dr. Goddard added, “What is
very important is to know that this is not going to be suitable for everyone. It should be acknowledged that not all people will want to self-manage and this will not be appropriate for those with advanced disease with ongoing complex treatments.” However, she said that in breast cancer, 80% of patients are in self-care with open access to support. She added that it is necessary to have a reliable, quality-assured check system in place to ensure that women are attending mammograms and informing of any symptoms or quality of life concerns. The NCSI often uses a nurse-led system where women are contacted by telephone. They are also given lifestyle recommendations and information on how to re-access specialist services, if required.

**Reducing the Burden of Long-Term Consequences of Treatment**

Dr. Goddard said that all patients must be informed of possible consequences of treatment at the beginning and the end of their primary treatment. They must be aware of warning signs of adverse effects such as lymphoedema, osteoporosis, sexual/menopausal problems and cardiotoxicity. The process is designed to emphasise prevention or early detection of consequences of treatment in order to be able to address any problems early on. This information must be shared with the women’s general practitioners. Women must also have access to specialist services for complex complications.

**Supporting Patients with Active and Advanced Disease**

Dr. Goddard said that any woman that develops recurrent or metastatic disease must receive the same high-quality support, rapid access back into the system and have her case discussed by a multidisciplinary team. There must be multi-professional assessment of her needs and care planning. She must have access to a cancer nurse specialist, and be effectively referred to the end-of-life care services, if necessary.

**Is self-management safe?**

The survivorship approach was introduced in nine pilot sites across England in 2010. Prior to that, a self-management follow-up system was introduced in the Bath Breast Unit in 2003 and results since then have shown that rates of recurrence have not increased compared with rest of England. Furthermore, survival rates are higher than average, with a 10-year survival rate of 90% in 2012. Dr. Goddard noted, “Patients find a particular benefit from the health and well-being and Moving On Days.”

The National Institute for Health and Clinical Excellence (NICE) produced its Quality Standards for Breast Cancer in 2011 in which it promoted survivorship. In September 2013, it published findings showing increased quality of life and improved productivity. Dr. Goddard added, “Instead of spending a lot of money bringing people back to an outpatient clinic you can really invest that resource into better and ongoing supportive care.”

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**Take home messages**

- There is an increasing number of breast cancer survivors with significant unmet needs from disease and/or treatment
- Most patients can be self-managed with appropriate support, information and education in place of traditional regular follow-up in hospital clinics
- Self-management has shown equivalent or improved recurrence and survival rates compared with traditional follow-up

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**For more information**

[www.ncsi.org.uk](http://www.ncsi.org.uk)
The Breast Health Day campaign

In her overview of the Breast Health Day campaign, Susan Knox, Executive Director of EUROPA DONNA, said that the global reach of this Europe-wide prevention campaign is on the rise. On Twitter alone it had a reach of more than 1,334,158. The social networks are ideal for spreading the digital message, on top of the Breast Health Day activities held in at least 28 of EUROPA DONNA’s member countries.

The Breast Health Day campaign promotes breast cancer prevention through healthy lifestyles in women and girls. Ms Knox cited International Agency for Research on Cancer estimates that about 30% of breast cancers could be prevented through healthy lifestyles throughout a woman’s life and starting in childhood. The campaign promotes those lifestyle factors found to influence breast cancer prevention: physical activity, maintaining a normal body weight, nutrition and limited alcohol intake.

The 2013 campaign, with the slogan “Make Good Choices for your Breast Health”, featured a new snappy, animated video showing how to make healthy choices. Based on images, the video was designed for easy use in all countries, by people of all languages. It ended with a frame with “For Your Breast Health” in 27 languages. Through www.breasthealthday.org, people could send in personal breast health messages. Another video of the infographics also brought a more upbeat approach to the statistics on breast cancer.

Also in 2013, to spread the message even further, the Breast Health Day leaflet and poster were translated into Czech, Italian, German, French, Russian, Swedish and Tajik. The press release was distributed using a PR Newswire service and it was translated into French, German and Spanish. Ms Knox encouraged advocates to use the materials to continue promoting prevention: “This is not a programme that should take place on one day. It is meant to take place all year long.”

EUROPA DONNA also continued to bring the Breast Health Day and the importance of prevention to the European Parliament. This year ED held the annual Information Day in Brussels on 15 October in cooperation with the French group Ruban de l’Espoir – Ribbon of Hope. All European Parliamentarians received the Breast Health Day leaflet in their mailboxes. Ms Knox added that the Coalition also actively promotes prevention at meetings throughout the year, such as at the European Breast Cancer Conference and all European patient meetings.

Ms Knox then passed the floor to two ED fora members to present the activities they held for Breast Health Day.

EUROPA DONNA France night-time cycling event

In a lively presentation, Elisabeth Marnier of ED France described the event: “Tous à vélo pour nos lolas” – “All on our bikes for our boobs”. They created the event in the city of Lyon in September 2011 in collaboration with La Ville à Vélo and since then have held 5 cycling events. She said it is a simple concept, a guided night-time bike ride through the centre of Lyon, supervised by volunteers from La Ville à Vélo. Twice a year more than 100 people dress in pink, sport pink cycling vests, and head out on bicycles for some active fun. Ms Marnier said it is a great way to promote physical activity to prevent breast cancer, to remedy fatigue and to inform participants about breast cancer screening. The presentation ended with an enthusiastic display from advocates translating the slogan into their own languages.

EUROPA DONNA Switzerland – Urban training

Maricel Marin-Kuan of ED Switzerland described the outdoor Breast Health Day activities held in Lausanne to the beat of a live band. The activities of urban training, Thai Chi and body balance helped younger people get the message about prevention. It was also a good opportunity to provide information on screening. Ms Marin-Kuan noted that the live band made for a good atmosphere and attracted people to the activities. She added that throughout the year they promote physical activity through weekly body balance and aquagym training for patients.

To put the physical activity theme to practice, advocates enthusiastically took part in a high-energy Zumba aerobics session.
Advocacy workshops

Advocates were able to share their ideas and know-how in a series of four workshops. The workshop rapporteurs provided the main conclusions from each group.

Advocacy for young women
Leaders: Mojca Miklavčič and Karen Benn

Forty-eight women participated in this workshop, each giving a brief account of the situation for young women in their country and their interest in young women’s issues.

Issues facing younger women
- Younger women often suffer from persistent psychological and physical problems long after breast cancer treatment. Many face emotional trauma, and physical and psychological treatment is as important as medical treatment. They often feel fear and uncertainty about the future.
- Body image can be a concern, including a woman’s own attitude to her body’s appearance, health, functioning, sexuality, attraction, all as components of a broader concept of herself.

Approaches to support
- At ED Slovenia, a young women’s group keeps in contact using online methods such as forums, Facebook, email, or telephone. This contact, regardless of the format, was felt to be important and effective.
- At ED Cyprus, support telephone lines specific to young women are available, as well as group meetings and outings. They “partner” young women who call with other young women in a similar life situation, such as those with young children. Professional psychological support is also available. The group regarded specific partnering to be very useful.
- At ED Czech Republic, they hold weekends away for the young women and their partners and families. A babysitting service is included so that young women can actively participate.
- ED Israel offers one-on-one support, as well as group meetings and weekends away. There is professional support about practical issues such as finance, insurance and work, as well as psychological support with specific emphasis on genetic counselling.
- ED Ireland has a dragon-boat team that enables women to make contact through an activity apart from breast cancer.
- ED Poland holds activities in secondary schools to talk about breast cancer with young women and girls.
- It was noted that it is important to have the appropriate legislative framework in place to protect young women against discrimination, especially regarding work.

Advocacy for women with metastatic breast cancer
Leaders: Evi Papadopoulos and Gertrude Abela

Approximately 40 advocates participated in this workshop and concluded that the number one need of women with metastatic breast cancer (MBC) is to receive more information and support. Other main points raised are summarised below.

Patient-health care worker relationship
- Quality of life is what women value the most and the terminology “chronic” is preferable to “incurable”.
- The doctor should inform the woman about the state of her health and women should be prepared to ask questions. This is preferable to using Internet or comparing cases with other patients.
- ED should continue to advocate for a breast nurses specialised in MBC, and breast units for MBC, or as a section within a breast unit. Some women may prefer to have consistency and continue with the same breast nurse as in their treatment for early breast cancer.

Support for women with MBC and their families
- In addition to support from doctors, breast nurses and psychologists, patient support groups help women share experiences with others who understand. Other methods include help-lines with backup nurse support, and an Internet forum with a separate version for women with MBC so that everyone can express themselves fully.
- The activities and support for family members depend on their ages and needs. Activities in various countries include a leaflet “Men Against Breast Cancer”, a course for partners, groups for family members that involve the men in the support, and art therapy support groups for children.

Materials
- ED France has created a brochure about MBC with input from oncologists, radiotherapists, psychologists and patients. This is available on www.europadonna.org.
- ED Cyprus produced a booklet for family members.
- ED Italy performed a survey about quality of life and the effect of treatment. Respondents were an average age of 54 years and requested more information from the oncologist; wanted the doctor to be sympathetic and to listen to them; wanted less bureaucracy, faster care and sharing of the treatment plan.

Guidelines, clinical trials and MBC registries
- Many aspects of MBC are already covered in the current issue of the EU guidelines and can be used for advocacy. These are described in EUROPA DONNA’s metastatic breast cancer annex to the “Short Guide to the EU Guidelines”.
- MBC will be included in the upcoming edition of the EU guidelines.
- In many countries, breast cancer registries do not specify metastatic disease.
- More information is required on clinical trials for MBC.
Advocacy and Survivorship

Leaders: Roswitha Britz and Dorothy Goddard

This workshop brought together about 50 women to discuss survivorship and the great differences between follow-up care from country to country. Below are the main points raised.

Follow-up and support

- Most women by and large self-manage but would feel more confident if they could have an annual visit with a key navigator, ideally a breast nurse, to guide them
- Women need to have confidence in a robust recall screening service
- Good literature and a clear pathway are necessary to support women, and ongoing support often comes from groups like EUROPA DONNA
- Specialist breast units and the European accreditation process are key to implementing good follow-up and support. The UK’s National Cancer Survivorship Initiative self-management approach is a good model to follow

Health and well-being

- Survivors in general do not feel sufficiently informed to monitor their own physical health for signs of recurrence/progression, consequences of treatment, etc. and often must find “extra” information on their own
- There is a general lack of services supporting the psychological consequences of disease
- Doctors often give approval for women to go back to work when they are still recovering and do not feel well; some lose their jobs
- There is a lack of psychological support for partners and family members. Care givers often themselves develop serious problems due to stress, and sexuality can be an issue
- People should not be left to their own devices and the health system should advise women as to where to go and what to do when they encounter problems; this work should not all be left up to non-profit organisations
- Continued lobbying for the accreditation of specialist breast units is important, as units must provide information and survivor support as part of their services. Advocates can argue to politicians that money will be saved in the long run by providing these services upfront

Sharing and learning

Breast cancer survivors share their experiences with others in many different ways throughout Europe:

- ED Malta hosts monthly survivor meet-ups and promotes positive body image through fashion shows
- ED Sweden hosts forums in which patients have the opportunity to meet with and ask questions of clinicians
- ED Austria takes an opportunistic approach due to the stigma attached to breast cancer in that country through programmes such as “Breast Friends”, Mona’s Blog, and provides email contacts so people can ask questions directly
- ED Ireland uses social media, a glossary of terms and promotes social events
- ED UK gives practical support through stressing the importance of training clinicians. Doctors learn from other doctors

Advocacy for special populations

Leader: Nicole Zernik

This workshop had 23 participants and first set out to define special populations as those with different needs, whether due to health, financial or religious reasons. Some examples given included women with disabilities, such as mental, physical, social and learning disabilities; different cultural, religious background or language; illegal immigrants; displaced people; women living under the poverty line; women in prison; older women; and men. It was concluded that ED Fora must take women with special needs into account in their advocacy activities. Below are some of the main points raised:

Identifying populations

- ED Cyprus has been contacted by an association for the hearing impaired for information on breast cancer
- In Kyrgyzstan there are remote regions where education is limited and help is needed
- ED Tajikistan is working with women with mental disabilities
- ED France is working with special populations that do not have access to health care

How to reach special populations

- ED France has translated a leaflet on mammography screening into Turkish and Arabic
- In the UK, advocates speak in schools to educate children so that they explain to their mothers about breast cancer and the importance of mammography screening. They have also translated information on prevention into 41 languages
- ED Ireland created a brochure on “9 things you should know about breast cancer” in simple language with pictures to address people of all educational, cultural and socioeconomic background
- In Czech Republic, at the Prague breast unit, they examine women from Vietnam, ask them questions in their language and have a Vietnamese translation of information
- ED Macedonia created a brochure in Braille for the visually impaired
- Screening programmes must also reach minority groups, through translation of invitation letters, for example, since screening participation tends to be low
- Women from different religious group could be contacted through their religious leaders

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About EUROPA DONNA

EUROPA DONNA – The European Breast Cancer Coalition is an independent, non-profit organisation whose members are affiliated groups from countries throughout Europe. EUROPA DONNA works to raise public awareness of breast cancer and to mobilise the support of European women in pressing for improved breast cancer education, appropriate screening, optimal treatment and care and increased funding for research. EUROPA DONNA represents the interests of European women regarding breast cancer to local and national authorities as well as to institutions of the EU.

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