Highlights from the 16th Europa Donna Pan-European Conference
“Breaking Barriers Starts With Us”

Zagreb, Croatia – 28-29 October 2023
More than 200 advocates from 32 countries spent an action-packed weekend at the Europa Donna Pan-European Conference in Zagreb, Croatia, in the company of other advocates, breast cancer experts and the European Commissioner for Health and Food Safety. Held 28-29 October, it was the Coalition’s first in-person Pan-European conference since the pandemic and was themed “Breaking Barriers Starts With Us.” The programme provided the evidence base – from European policy and guidelines to disparities in care, survivorship, and the latest science – to build advocacy campaigns to improve breast cancer care and erase the wide disparities between countries and regions, and between the subsets of patients with breast cancer, such as younger and older women, and those with metastatic disease.

Sessions and panel discussions with experts in all areas of breast cancer were designed to provide the tools needed to “break down the barriers”. Marzia Zambon, Europa Donna Executive Director, told the advocates present, “Once the barriers are down, the logical thinking is to create pathways and build bridges. As advocates and people living with and after breast cancer, the most effective service we can provide is to create alliances – with policy makers, payers, other patient organisations, researchers, oncologists, pathologists, surgeons, nurses, industry, insurance companies and patients.” This report provides the main points and key messages from the conference presentations.

The Europa Donna Pan-European conference is held every 2 years and brings together patient advocates and breast cancer experts from the Coalition’s 47 member countries.

Update on Europe’s Beating Cancer Plan – The Path to Better Breast Cancer Care: Successes and Challenges to Come

As the keynote speaker, Stella Kyriakides, EU Commissioner for Health and Food Safety and a former Europa Donna President, spoke from her role as Commissioner but also as a breast cancer patient advocate. “There are fewer organisations closer to my heart than Europa Donna, which has been part of my life for decades,” she said. Reminding participants about the progress the Coalition has made – from an initial handful of country members to the 47-country strong network of thousands of women, families and health care professionals it is today. Europa Donna is a living example of how a joint Europe-wide commitment can work to further a common public health cause. “Let us keep on breaking the barriers together,” she said.

In this light, she summed up the recent major accomplishments in Europe and goals for the near future. Many fall within the scope of Europe’s Beating Cancer Plan which was launched in 2021 and is dedicating over 4 billion euros to cancer care by creating and backing key initiatives in prevention, early detection, diagnosis and treatment, and quality of life of patients and survivors. For prevention, she cited
Milestones Achieved and in the Making

- **Council Recommendations on Cancer Screening** in vigour as of December 2022
  - By 2025, offering 90% of those eligible breast cancer screening
- **Cancer Imaging Initiative** launched in December 2022
- **ECIBC European Guidelines on Breast Cancer Screening and Diagnosis**, updated regularly
- Updating of the **European Code Against Cancer** under way
- An **EU Joint Action** toward a network of Comprehensive Cancer Centres
- **Cancer Inequalities Registry** gathering data, with the first report due in January 2024
- A plan to establish an **EU code of conduct** on fair access to financial services

For early detection, the Commissioner said that a defining moment for her came in December 2022 with the update of the **Council Recommendations on Cancer Screening**. This comes 20 years after she took part in the discussions for the first EU cancer screening recommendations. Now, for the first time, these updated recommendations set the goal of offering breast, cervical and colorectal cancer screening to 90% of those eligible in the EU by 2025. They also recommend extending the target ages of breast cancer screening programmes to include women aged 45 to 74 years. To accomplish this, funding is designated from the EU4Health programme, a large part of which will go to a Joint Action involving EU member state authorities. This is currently being set up.

Other key initiatives include the **European Guidelines on Breast Cancer Screening and Diagnosis**, part of the **European Commission Initiative on Breast Cancer** (ECIBC; see more on this on page 6). As part of the Cancer Plan there is also an **EU Joint Action** to establish a network of Comprehensive Cancer Centres that aims to give patients easier access to high-quality diagnostics and innovative treatments. Also under the Plan, a **Cancer Imaging Initiative** was launched in December 2022 to create a European infrastructure of cancer image data for health care providers and researchers. In September 2023, the first prototype of the **Cancer Europe Image platform** went live and is now linking images and datasets on breast cancer and other cancer types.

To address the persisting inequalities between countries and regions, the Cancer Plan’s **Cancer Inequalities Registry** is gathering data to pinpoint trends, disparities and inequalities, based on indicators such as gender, age or socioeconomic status (for more on this see page 5). Its findings will be used to guide future policies and investment to tackle and overcome these inequalities. "In 21st century Europe, it is unacceptable for access to screening or to diagnosis and treatment to be dependent on where you are born or on other factors over which you have no control," Commissioner Kyriakides said.

She nonetheless reminded advocates of the achievements of earlier detection programmes and considerable reductions in deaths due to breast cancer in recent decades, adding that “The Cancer Plan proposes shifting the debate from focusing only on survival of patients to also considering their quality of life during and after treatment.” In this regard, patient organisations have been reporting the need for access to financial services. In response, there is a plan to draft the first EU code of conduct on fair access to financial services for people who have had cancer, otherwise known as “The Right to be Forgotten”. The code of conduct will be based on a series of roundtables held up to March 2024. Europa Donna has been selected as a stakeholder in this initiative. Advocates will need to play a large role in ensuring that it inspires binding legislation at the national level.

Commissioner Kyriakides encouraged the advocates present to seize the opportunity that the EBCP offers for advances in breast cancer care. “Europa Donna has been and remains trailblazers in the work to raise awareness of the challenges and to promote solutions,” she said. “And for us, here, wearing pink is not just a colour, it is an attitude. It is about hope and determination. We have a huge opportunity in Europe and we cannot fail.”
In a powerful session dedicated to Europa Donna’s Cancer Currency Campaign (www.thecancercurrency.com) to draw attention to the unmet needs of women with metastatic breast cancer (MBC), the protagonists of the campaign each told a piece of their story and bravely called for the Commissioner and European institutions to act now in advancing policy for MBC. Each ended with a specific request. It was an emotional moment culminating in a long and moving standing ovation.

The campaign, launched by Europa Donna in June 2023, involves a series of five banknotes, each inscribed with the stories of five women living for over 5 years with MBC. It aims to show that the life of each person with MBC has value—they must not be given up on. Those living with MBC have been left under-funded, undertreated and underserved, even though their lives still hold immense value.

Claudia, one of the protagonists, highlighted how unique and important this MBC campaign is. Most campaigns and media attention focus on early breast cancer and not on those living long term with MBC as a long-term disease. This stage of breast cancer needs visibility, hope and solidarity as the group is living longer and growing thanks to new treatments and combinations. Her call for change to the European community: see me!

For her part, Carla and her oncologist had to make a treatment decision that would impact the length of her life but had no data to support it. European health systems do not measure MBC. It is important for data to be captured from diagnosis onward in order to gather real-world evidence. Her call for change: count me!

Joyce feels a lack of psychological and emotional support in the more than 7 years she has lived with MBC. On social media there is too much silence about metastatic disease. Until recently, she had no one to turn to for medical advice off-hours or at weekends. Her call for change: support me!

Paola experienced problems with her eye but, initially, found that no doctors would take responsibility for her condition. Finally, she was diagnosed with ocular MBC. Europa Donna supported her more than any doctors. Her call for change: enable the community to treat me!

Sadly, Simona passed away shortly after telling her story and recording her interview for the campaign. Speaking on her behalf, her sister and niece said that while it is too late for Simona, many people with MBC need help. Their request: act now to help people living with MBC before it is too late!

Simona’s sister then presented Stella Kyriakides with their banknotes from The Cancer Currency. Clearly moved by the campaign and stories, the Commissioner addressed the women and the audience: “I want to say thank you because I feel humbled. It’s difficult not to feel overtaken by the emotion that many of us are feeling in this room. I want to thank you for honouring us with your stories and I know that there are other people in the room today who are living with metastatic breast cancer. I want to honour you too.” She added that breast cancer is not all pink, but includes women with advanced and metastatic disease, and those who have left us. “I want to thank Europa Donna for putting together this campaign and putting a face to metastatic breast cancer and to the women living with this disease.” She encouraged advocates to gather together because the Commission can do something. For instance, she said that for the first time, metastatic disease has been included in Europe’s Beating Cancer Plan and there is dedicated funding. Yet much work remains to be done.

The Cancer Currency is an ongoing campaign targeting policymakers, who can make positive changes for people with this disease, as well as the general public who need improved awareness of MBC and can help the message reach policymakers. People are asked to share the currency found on www.thecancercurrency.com via social media. The statistics on the shares gathered globally and the overall awareness will then be presented to policymakers to further influence improvements for MBC care.

- 20-30% of those with early breast cancer go on to receive a metastatic diagnosis regardless of steps taken
- 10% of people have metastatic breast cancer at first diagnosis
- Average survival rates stand at 2-3 years
- Life goes on after a metastatic diagnosis
Providing evidence for the inequalities mentioned by Commissioner Kyriakides, Bettina Borisch, from the MPH Institute of Global Health, University of Geneva, Switzerland, and Executive Director of the World Federation of Public Health Associations – and also a past Europa Donna President – said that the greatest cause of ill health is inequity, not genetics, for instance. The link between socio-economic status and health is linear: the better off you are the better your health. This is due not only to economic factors but also to education, living conditions and access to green space, for example. Inequalities are avoidable and do not accrue randomly, but due to circumstances people cannot address individually. Yet in Europe, data from the European Cancer Inequalities Registry show wide disparities in breast cancer mortality that cannot be explained by GDP: rates are high in Luxembourg and Germany, for example, and low in Scandinavia and the Iberian peninsula. “So, the income level of a country is not the be all and end all,” she said. However, regional data show that individuals with higher income are more likely to survive a breast cancer diagnosis. What influences this? Access to early detection, diagnosis and treatment. On the opposite end, limited access to health care and supplies, fuelled by lack health care insurance coverage, high “out-of-pocket” spending, waiting times, and geographical disparities in services can be detrimental factors. To address this, advocacy can aim to undo the causes, prevent them, and then use individual experience to try to mitigate them.

What Else Can Advocates Do?

From a policy perspective, Tit Albrecht, from the Centre for Health Care, National Institute of Public Health in Ljubljana, Slovenia, said that one of the ways to overcome inequalities nationally and internationally is to promote and improve health literacy, i.e., where people can easily understand medical explanations, process information, and adapt their lives as needed for their condition. An example of this is the ED Pan-European conference itself. The experiences of the women in the MBC Cancer Currency campaign are an example of how patients can be drivers of progress toward better quality of life and outcomes. To show what is important to patients, they should be asked to record their experiences using questionnaires such as patient-reported experience and patient-reported outcomes measures (PREMS and PROMs). A European Partnership for Action Against Cancer (EPAAC) survey of EU member states revealed that patients are poorly involved in national cancer plans. The goal now is to involve patients in all phases of preparation and implementation of such plans, and to intensify networking and patient presence in all areas of cancer research and control.

What advocates can do to overcome inequalities nationally and internationally

Tanja Spanic, Europa Donna President

- Identify stakeholders for their own country (eg, policymakers, researchers, health care professionals)
- Share good practices, facts and knowledge
- Practice evidence-based advocacy
- Share learnings with other ED countries and beyond
- Collaborate with partners beyond ED countries (eg, national/EU/international research organisations, scientific societies, other patient coalitions, sponsors, policymakers)
Where Are We With the European Breast Cancer Guidelines and Quality Assurance Scheme?

Bettina Borisch, who is also a member of the ECIBC Guideline Development Group, then gave an update on the ECIBC European breast cancer guidelines which are now being implemented or considered in 10 countries inside and outside the EU. She described the stringent development process for these evidence-based, expert-led guidelines that are constantly updated and revised on the dedicated guidelines platform. Their implementation — and overcoming the barriers to this — is the next step. ED’s Executive Director Emeritus Susan Knox is a member of the Guidelines Development Group. Prof Borisch said that patients — and specifically breast cancer advocates — have paved the way for these recommendations. The guidelines are an achievement because they are evidence-based recommendations, developed by an international working group that includes patients and women. They focus on outcomes that matter to women, and consider cost, feasibility and need in a living document that is updated as evidence emerges. Advocates are key to having these recommendations implemented and the recommendations are a fundamental tool for advocacy. Because of this, Europa Donna teaches advocates how to read the EU guidelines at its annual Advocacy Training course.

Stepping Stones that Paved the Way to the New European Guidelines

- Previous EU guidelines: focused on breast cancer screening and diagnosis, in paper format; expert recommendations not always evidence based
- 2003 and 2006 EU Parliament Resolutions on Breast Cancer, with significant influence of ED
- 2008: Council of the European Union asked the European Commission to establish the ECIBC. ECIBC to create evidence-based breast cancer recommendations, new European guidelines and a European Quality Assurance Scheme for breast cancer services
- 2014: Public call for working group members (professionals, methodologists, individuals)
- 2015: Guidelines Development Group (GDG) and Quality Assurance Scheme Development Group (QASDG) formed and kick-off meeting held. Project co-ordinated by the Joint Research Centre (JRC), the science and knowledge service of the European Commission, in Ispra, Italy
- 2016: First 4 recommendations released
- 2021: Completion of the European Guidelines on Breast Cancer Screening and Diagnosis with a total of 74 recommendations and 4 good practice statements
- 2022: Third update of the guidelines
- Several meetings held every year
- Guidelines developed to cover the full care pathway

Steps Used to Create Guideline Recommendations

- PICO format (Population, Intervention, Comparison, Outcomes) — technique used in evidence-based practice to frame and answer a clinical or health care-related question and to develop the relevant literature search strategies
- Cochrane Iberoamerica performs systematic review of related studies to inform decisions
- GRADE (Grading of Recommendations Assessment, Development and Evaluation) guidelines development tool used by GDG to develop recommendations
- GDG assesses the evidence and makes recommendation with varying strengths (eg, low to high)
- Recommendations are constantly updated as new evidence emerges
Another main element of the ECIBC is the **Quality Assurance Scheme** which establishes quality and safety requirements for breast cancer services that can then be certified. Robert Mansel, Emeritus Professor of Surgery from Cardiff University School of Medicine in the UK and Chair of the Quality Assurance Scheme (QAS) Development Group, described the feasibility checks and pilot testing of the breast centre requirements and certification process. Following its creation in 2015, the QAS Development Group, which includes individual members from Europa Donna, worked to establish the service requirements. These were included in the **Manual for Breast Cancer Services** and underwent feasibility checks within breast centres until April 2022. The testing phase of the scheme ended in March 2023 with 20 entities in total participating from nine EU countries. In the pilot programme, each breast cancer service collaborated with an allocated certification body, which performed an audit to check the compliance. The pilot showed that the audit process was both useful and relevant for improving services and it was determined that the QA scheme is “fit-for-purpose”. As feedback, some centres suggested making clearer which criteria are mandatory vs recommended and noted that they require access to better IT tools to assemble data. The scheme and its manuals are now being revised to include relevant feedback. Prof Mansel said that having an external audit can be helpful so that providers know if their centre really is of high quality or not. He added, “It has been 8 years of hard work, and it will eventually benefit women in Europe.” Validation of the Quality Assurance Scheme by European Accreditation is expected in 2024. ED’s Executive Director Marzia Zambon is a member of the QAS Development Group.

**Next Steps**
- Validation of the EU Quality Assurance Scheme by European Accreditation is expected in 2024
- The goal is for women to have access to a list of certified centres where they can receive high-quality breast cancer care that meets the pre-specified EU standards
Breast Imaging Innovation

From AI to Risk Factor Customised Screening

Mireille Broeders, Professor of Personalised Cancer Screening at Radboud University in The Netherlands, said that artificial intelligence (AI) will find its way into breast cancer care and screening as it has many applications, particularly for repetitive tasks, and provides a reliable outcome. This could free up radiologists’ time. (NB: the European Guidelines on Breast Cancer Screening and Diagnosis conditionally recommend using double-reading with AI support for digital mammograms or tomosynthesis.) A study on women’s preferences for AI use in mammography screening showed that almost 78% wanted a radiologist to examine the findings. Another use of AI could be to determine breast cancer risk, which for example is supported by a study using an AI-based risk model compiling mammogram characteristics. This type of AI application could help in offering women screening according to their risk level as well as offering prevention measures for those at high risk. For instance, the screening ages or intervals could be adapted, or specific imaging modalities be applied, to fit a specific risk factor (eg, dense breasts). An EU research project in this area is MyPeBS (My Personal Breast Screening), an international project and clinical study comparing personalised risk-based screening vs standard screening. Europa Donna is a member of the Independent Ethics and Data Monitoring Committee for this study.

Do women want to know their risk? Surveys show that while a large majority do want to know their risk, not all do. Women with a low risk show reluctance to being offered less intense screening or being excluded from screening. More research is needed in risk-based screening and AI. “Training and communication are key,” Prof Broeders said. “This is a role for advocates and how to communicate a risk-based screening approach to women will be fundamental.”

The Challenge for Radiologists: Dealing With Risk Factors Such As Dense Breast

Alexandra Athanasiou, Head of Breast Imaging Department at Mitera Hospital, Greece, reminded advocates that the European breast cancer guidelines are designed for women at average risk of breast cancer. She ran through four different scenarios for screening for above-average risk: predetermined risk (eg, hereditary mutations), history of breast cancer, specific lesions that increase risk, and dense breast tissue. The 2023 American College of Radiology (ACR) screening guidelines recommend annual MRI surveillance starting at age 25 to 30 in women with genetic mutations, those with a calculated lifetime risk of 20% or more and those exposed to chest radiation at a young age. These women are also eligible for annual mammography screening starting at ages 25 to 40, depending on type of risk. The ACR also recommends an annual supplemental MRI in women diagnosed under age 50 or those with a personal history of breast cancer and dense breasts.

New European guidelines developed by EUSOMA, EUSOBI, ESP (BWG) and ESSO include recommendations for radiological detection and follow-up of high-risk lesions, as well as recommendations for their management.

Regarding dense breasts, mammographic density of breast tissue is graded (a to d, low to high) and additional factors (eg, hormone status, genes) can be added when calculating risk. A study showed that among women with the highest degree of breast density there was a 6 times greater incidence of interval cancer (ie, between mammography screening rounds) compared with the lowest density. However, studies indicate a 12% false-positive rate when ultrasound is added to mammography, and 8% for supplemental MRI. Dr Athanasiou pointed out that the EU breast cancer guidelines do not recommend additional ultrasound or MRI screening for dense breasts based on a need for further research and randomised controlled trials in this area. However, the EUSOBI (European Society of Breast Imaging) guidelines for extremely dense breasts recommend, based on level I evidence, informing women about their breast density and offering supplemental screening, preferably with MRI every 2-3 years. Dr Athanasiou concluded that we need more data and research, equal access to screening and well-trained radiologists.

Guidelines to Keep an Eye on

European Guidelines on Breast Cancer Screening and Diagnosis


European guidelines for the diagnosis, treatment and follow-up of breast lesions with uncertain malignant potential (B3 lesions) developed jointly by EUSOMA, EUSOBI, ESP (BWG) and ESSO. Eur J Surg Oncol 2024, 50:107292.
When Breast Cancer Hits: Different Ages, Different Issues

A session was dedicated to the needs of younger women (i.e., pre-menopausal) and those of post-menopausal and older women and used specific cases for discussion. Representing post-menopausal women, ED Executive Director Emeritus Susan Knox described her personal experience with being diagnosed both pre- and post-menopause. Given the wide range of needs of women in post-menopause, she said that treatment needs to be individualised, not based on chronology, and must consider quality of life, lifestyle and comorbidities. When diagnosed later in life, a woman may be more independent and resilient, with time to dedicate to recovery – and fertility is no longer an issue. She said that more research into adverse effects of therapy and how to manage them is needed. Advocacy should focus on individual treatment plans, adequate follow-up and ongoing screening. There needs to be better access to and more research regarding complementary therapies in alleviating side effects of long-term therapy so that these can be covered by health systems. She said, “We need more evidence to support exercise and alternative therapies to support therapy, and to encourage good habits that can be used later in life.”

Laura Biganzoli, Director of the Breast Centre at the Oncology Department of the Hospital of Prato in Italy, then presented a case of a 76-year-old woman in order to draw attention to the plights of older women diagnosed with breast cancer. Data are lacking in this group, and age may determine their access to therapy. In the panel discussion, it was noted that there is ageism, i.e., a negative view of older age, especially for women, yet the time between 60 and 90 years and 30 and 60 is the same.

Fedro Peccatori, Medical Oncologist and Director of the Fertility and Procreation Unit, European Institute of Oncology in Italy, presented the case of a 33-year-old woman with breast cancer and a BRCA2 variant who underwent oocyte cryopreservation before adjuvant chemotherapy. Important questions in such cases include the effect of treatment on personal and social life, sexuality, work life and effect on future fertility. Having a high-risk genetic mutation leads to questions on future cancer risk, the risk for cancer in offspring, and timing for risk-reducing removal of the ovaries and fallopian tubes. He noted that the effect of some of the newer therapies on fertility is not yet known.

Tanja Spanic, President of Europa Donna and diagnosed at the young age of 26, gave the young woman’s perspective, and the fact that women under 40 are rarely included in clinical trials. An exception is the POSITIVE study that provided evidence for stopping endocrine therapy to enable pregnancy in younger women. Tanja said it is important to advocate for personalised treatment and preferences when diagnosed, regardless of age. Women need to be made aware of and have access to fertility preservation. For more on this topic see the Europa Donna White Paper: Cancer and Family Planning.

- Almost 80% of women diagnosed with breast cancer are post-menopausal
- There is a lack of data for younger and older women with breast cancer
Survivorship and Quality of Life: How to Help and Who to Ask for Help

Given the growing number of people who are living long after a cancer diagnosis and therapy, long-term quality of life (QoL) needs to be addressed. Davide Soldato, a medical oncologist from Gustave Roussy Institute in France, outlined the latest approaches to manage side effects of therapy (see table below). Any assessment should include these, alongside psychosocial factors and comorbidities, as well as long-term effects, such as cardiac toxicity, cognitive dysfunction, neuropathy and mood disorders. For vulvo-vaginal symptoms use of vaginal low-dose oestrogen is not universally endorsed and should be discussed on a case-by-case basis. Recent prospective studies on cognitive impairment (so-called chemo brain) indicate that it may not all be chemotherapy-related but depend on various factors: changes begin before chemotherapy, and they can be exacerbated and prolonged by hormonal therapy. Effective interventions are lacking, but organisational strategies can help. Women should be referred for neurocognitive assessment and neurorehabilitation. Regarding depression and anxiety, the risk is higher in younger women, closer to diagnosis, and in those treated with chemotherapy. Interventions include medication, psychotherapy and mindfulness-based approaches. Fatigue for its part can be intertwined with depression, sleep disturbance, pain and cognitive issues. It is different from normal non-cancer fatigue as it is not remediated through rest and sleep. No pharmacological approaches have shown a benefit; the most evidence supports physical activity. Dr Soldato said that collaboration with patient advocates is fundamental to understand and integrate patient perspectives on the side effects that affect their QoL and to individualise treatment options.

Side effects of therapy and approaches that have shown a benefit

<table>
<thead>
<tr>
<th>Vasomotor symptoms (hot flushes)</th>
<th>Vulvo-vaginal symptoms</th>
<th>Cognitive impairment</th>
<th>Distress, depression, anxiety</th>
<th>Fatigue</th>
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<tr>
<td>Low dose antidepressants (with caution in those on tamoxifen)</td>
<td>Vaginal lubricants</td>
<td>Lifestyle (increased exercise, limit alcohol intake)</td>
<td>Medications</td>
<td>Moderate physical activity</td>
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<tr>
<td>Cognitive behavioural therapy (CBT)</td>
<td>CBT</td>
<td>Organisational strategies</td>
<td>Mindfulness meditation (depression)</td>
<td>CBT</td>
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<tr>
<td>Hypnosis</td>
<td>Laser therapy (but quality long-term data lacking)</td>
<td>Brain fitness exercises</td>
<td>Psychotherapy</td>
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The PREFERABLE Project*

On the topic of physical activity, exercise and MBC, Anne May, Lead Researcher of the PREFERABLE project, The Netherlands, provided evidence supporting the beneficial effects of physical activity on QoL and secondary prevention in breast cancer. High level studies support the benefits of aerobic and resistance exercise in improving anxiety and depressive symptoms, fatigue, QoL and physical functioning. However, these finding are for early cancer, while studies in the metastatic setting are lacking.

With this in mind, the PREFERABLE Project (Project on Exercise for Fatigue Eradication in Advanced Breast cancer to improve quality of life), in which Europa Donna is a partner, has performed a randomised controlled trial of the effects of structured and individualised exercise on fatigue and QoL in patients with MBC. This included a moderate-to-high-intensity exercise programme using, eg, stationary bikes plus resistance and balance exercises. The results were being presented at the San Antonio Breast Cancer Symposium in December 2023. Dr May revealed that participants were able to adhere to the 9-month exercise programme and many continued exercising afterward. The PREFERABLE Perspective study, with the help of Europa Donna, gathered information on attitudes and knowledge about exercise and MBC, and found that women generally had a positive attitude towards physical activity. Important barriers to exercising included feeling tired or weak and not having access to an exercise programme for cancer patients. Factors that helped included previous positive physical and emotional experiences from exercising and getting personal advice from a physiotherapist. Implementation of exercise programmes for women with MBC is the next step. “I will give you my evidence, but we need the voice of the patients to get this exercise programme implemented and have it reimbursed,” Dr May said.

Davide Soldato

Anne May

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* The PREFERABLE project has received funding from the European Union’s Horizon 2020 research and innovation programme under grant agreement No 825677
**Why and How Patient Advocates Can Get Involved in Research**

Given the need for patient advocates to be involved in research and the growing demand for their involvement in clinical trials, Ximena Montano, ED Board Member and a Principal Investigator and Lecturer at King’s College and Westminster University in London, UK, outlined the clinical trial process and how advocates should contribute to breast cancer trials from their outset.

### Trial Phases in Oncology and What Advocates Can Do

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<tr>
<th>Phase</th>
<th>Description</th>
<th>Advocate role</th>
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<td><strong>Phase 1</strong>: Small trials of few patients to test an intervention, its safety, side effects, effect in the body, effect on a tumour. Often recruiting patients with advanced cancer who have been on many previous therapies.</td>
<td><strong>Advocate role</strong>: Input into informed consent documents and ensuring women understand the potential risks and benefits of participating in a phase 1 trial. It is the most demanding trial phase because it involves many doctor’s appointments. Informed consent must be carefully constructed and communicated.</td>
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<td><strong>Phase 2</strong>: In a larger group of patients, further evaluation of safety plus efficacy, types of breast cancer in which it may be useful, best dose and regimen. It can include a comparison with a standard therapy (control arm).</td>
<td><strong>Advocate role</strong>: Encourage patients to report adverse events and recurrences. Important to check the quality control of data surveillance and cancer registries.</td>
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<td><strong>Phase 3</strong>: Compares a new therapy with an existing one in a large number of patients to test the efficacy and safety and the effect on quality of life. It is the last phase before regulatory approval.</td>
<td><strong>Advocate role</strong>: Provide input from the start, into the design of the protocol for the trial, the informed consent process, and possibly being included on the Independent Data Monitoring Committee.</td>
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<td><strong>Phase 4</strong>: Known as pharmacovigilance or post-marketing studies to monitor long-term toxicity of a drug/therapy. Patients need to be followed up and contacted and any adverse effects need to be reported.</td>
<td><strong>Advocate role</strong>: Ensure follow-up studies are being performed. Request quality-controlled data and surveillance and inclusion in cancer registries.</td>
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Ximena highlighted that all trials must have strong scientific committees. **Advocates should** check that trials in their country are being conducted according to the approved protocol, good clinical practice and all regulatory requirements. Trials should address questions that are of interest to women and should be representative of women in the population.

Although most drug trials are sponsored by the pharmaceutical industry, some studies by research networks, such as Breast International Group or the International Breast Cancer Study Group, are run by academia. Some countries/governments sponsor clinical trials. **Advocates should** check for trials being performed by academic centres and government in their own countries. They can encourage them to be involved in larger trial networks/consortia.

Some trials are not therapy-related and examine epidemiology and understanding better the disease, by for example, focusing on lifestyle factors that may influence breast cancer risk. **Advocates should encourage** the implementation of these trials and inform women how they can participate.

As a general recommendation, **advocates need to understand** the clinical trial process and remain well informed about scientific research. They should advocate for dissemination of study results and for effective drugs to be available across all countries. It is also important for advocates to be involved in clinical trials, eg, sitting on trial committees. To achieve this, **advocates should**:

- Develop relationships with researchers who will support the involvement of patient advocates
- Find collaborating partners
- Encourage advocates to attend breast cancer conferences

### Examples of some of the studies, networks and collaborations in which Europa Donna is involved:

- BIG Scientific Committee Meetings and BIG Projects (MINDACT, AURORA, POSITIVE and OLYMPIA trials)
- Early Breast Cancer Trialists Collaborative Group (EBCTCC) – Steering Committee
- International Breast Cancer Study Group (IBCSG) – Ethics Committee
- Horizon Projects: MESI-STRAT, PREFERABLE, INSPIRE, CARDIOCARE, SmartCare, DEFINITIVE, CINDERELLA
- European Patients Forum – current members and past members of the Executive Committee
- EBC Council – ED is a founding member
- European Cancer Organisation Patient Advisory Council – one ED representative
- ABC Global Alliance – current member
- TBCT multi-stakeholder initiative
- WECAN network
How Breast Cancer Treatment is Evolving

Natalija Dedić Plavetić, a medical oncologist at University Hospital Centre Zagreb in Croatia, described the complex and active area of research into therapies for the many different subtypes of early breast cancer and metastatic disease. She covered data on de-escalation, where patients can be spared aggressive treatment (e.g., chemotherapy), when little or no benefit will be gained. For example, use of gene expression assays can help to identify women at a low risk of recurrence and who would not benefit from chemotherapy. In this vein, patients with early HER2+ breast cancer may also be spared treatment with anthracycline.

Most studies, however, are on treatment escalation. In both early and metastatic oestrogen receptor-positive (ER+)/HER2- breast cancer, data support a combination of endocrine therapy (ET) and a CDK4/6 inhibitor. In early triple-negative breast cancer (TNBC), a neoadjuvant and adjuvant checkpoint inhibitor plus chemotherapy showed a benefit over chemotherapy alone using various progression and survival outcomes.

Dr Dedić Plavetić outlined the new treatment options in the metastatic setting, where not so long ago options were few. These include CDK4/6 inhibitors, PIK3CA inhibitors, PARP inhibitors, checkpoint inhibitors, and various antibody drug conjugates, with each approach being targeted at a specific MBC subtype. The antibody drug conjugates, which are more targeted therapy, are the most important addition of late and have shown a benefit in ER+/HER2-, HER2+, TNBC, HER2-low breast cancer. A newer subgroup, HER2-low, refers to tumours that do not surpass the threshold to be classified as HER2+. This accounts for some 45-55% of HER2-type breast cancers. An antibody drug conjugate has shown about a 50% lower risk of disease progression and death than with chemotherapy in this group. Dr Dedić Plavetić called for comparative data between the various antibody drug conjugates to help guide their use in individual patients and determine whether switching between them may be effective after progression has occurred on one of these therapies.

The Latest Updates on Breast Cancer Surgery

Fiorita Poulakaki, Vice-President of Europa Donna and a breast surgeon and Head of the Breast Surgery Department at Athens Medical Center, presented data showing that that there is also a trend towards de-escalating surgery. There are various ongoing studies on surgery vs surveillance for DCIS (ductal carcinoma in situ, usually a low-risk tumour) with the aim to find a balance between over- and undertreatment of these tumours. Another de-escalation trend came with paradigm-changing studies leading to no longer removing lymph nodes in the axilla but performing sentinel lymph node biopsy (SLNB) instead in most cases. For instance, in women with a positive sentinel node undergoing primary breast-conserving surgery, an almost 10-year follow-up found no difference in the risk for recurrence at the tumour site whether lymph nodes were entirely removed or only the affected sentinel lymph node was removed. In a study from 2023, women with small node-negative breast cancer based on ultrasound findings had very similar outcomes to those undergoing SLNB, suggesting that in a specific group of patients, axillary surgery may not be necessary. The Lucerne Toolbox 2, a multidisciplinary expert consensus in which Dr Poulakaki participates, concluded that axillary lymph node dissection can be replaced by SLNB in most scenarios. SLNB may still be worthwhile while the affected lymph node tissue can provide valuable information about the disease.

There is also escalation in surgery, with an increase in breast reconstruction and bilateral mastectomy rates. Breast reconstruction can be performed at the time of the primary surgery or delayed, as can other oncoplastic techniques such as reduction procedures to the unaffected breast to create symmetry. Such procedures can increase the length of the operation and have complications that may delay adjuvant therapy. But the cosmetic result is pleasing and has a positive psychological effect on the patient.

Regarding the increase in bilateral mastectomy rates, studies indicate that patient choice is the main driver, despite there being no evidence that bilateral mamatomastectomies prolong survival in women with sporadic breast cancer. The 13th European Breast Cancer Conference (EBCC-13) Manifesto, in which Europa Donna participated, includes a list of discussion points for patients considering having a contralateral mastectomy, including that such a procedure will not reduce the risk of the known cancer returning. The procedure remains a valid choice for women with hereditary breast cancer risk, but for many women it results from fear, exaggerated perception of risk and inadequate discussion and counselling. Multidisciplinary teams play a fundamental role in helping women make an informed decision.

Further Reading


What About Radiation?

Zrinka Rendić-Miočević, an oncology and radiotherapy specialist at Clinical Hospital Centre SM in Zagreb, outlined the latest in radiotherapy, a treatment used in more than half the women with breast cancer. Over the years, the radiation doses have decreased as has the duration of radiotherapy from 5 or 6 weeks to 3 weeks. This could decrease to a possible 1 week in the future due to changes in techniques. Boost is a technique where an additional radiotherapy dose is targeted at the area where the tumour has been removed. Simultaneous boost is delivered at the same time as the round of regular radiotherapy, often as a continuation. It is used in women with higher risk of recurrence and has been shown to reduce recurrence rates, but no advantage to date for overall survival. Dr Rendić-Miočević also described the intraoperative radiotherapy (IORT) approach in use in her hospital where radiation of the tumour bed is delivered in a single fraction immediately following surgical removal of the tumour, particularly for patients with a high risk of recurrence. This approach has been studied for more than a decade and has the advantage of precision and reduced radiation toxicity, while taking about 45 minutes after surgery. She added that IORT is not equivalent to and cannot replace usual external beam radiotherapy. It can be used in women with high risk of recurrence in whom whole breast radiotherapy is still mandatory after this procedure. It also requires having the IORT equipment installed in the operating theatre. She called for an increased number of radiotherapy machines and updating of equipment.

Genetic Testing Today

Iva Kirac, a surgical oncology specialist at the University Hospital of Tumours in Zagreb, Croatia, described the approach they use to test for hereditary gene mutations in breast cancer. Testing for BRCA1/2 mutations is necessary given that in individuals with these hereditary mutations have a 41-90% increased risk for breast cancer, as well as a high risk for ovarian cancer and prostate cancer. In those with breast cancer, there is a 27% risk of getting cancer in the unaffected breast. However, BRCA is not the only culprit given that a range of other higher risk mutations have been identified (eg, ATM, PALB2, TP53 and others). She said that in her centre they perform genetic testing for women with breast cancer who, for example, are under age 45, those under 50 with an affected relative, and those with two relatives with cancer. Among those who are healthy but have a family history of breast cancer, they check, for example, those with a high-risk score or a first-degree relative who is positive for mutations. They also test people with specific characteristics or who are undergoing specific therapies, such as those with TNBC, and those having PARP inhibitor therapy. As a testing technique they use next generation sequencing using a 113 gene panel, and other methods. Dr Kirac said that Croatian guidelines covering criteria and processes for genetic testing have helped set standards and led to reimbursement of this approach.
Focus on Europa Donna Fora Projects

The Europa Donna Pan-European Conference always provides an opportunity for advocates in member countries to spend time together, share strategies and projects. With this in mind, three ED Fora were chosen to present a specific project.

Mary Perdiou of ED Cyprus described her Forum’s fight against financial discrimination that insurance companies inflict on breast cancer survivors by limiting their access to various types of coverage. The “Right to be Forgotten” campaign featured press conferences, meetings with government representatives, insurance companies and other stakeholders, as well as a designated Pink Silhouette Walk. Insurance companies have since submitted a revised Code of Conduct and in Parliament an amendment has been filed to eliminate financial discrimination against cancer survivors.

ED Luxembourg’s Ingrid Krücken described their project to provide support to families of women undergoing breast cancer treatment. This is to address the unique needs of people in this country with a high breast cancer rate and a small population, 75% of whom are expats who may not have family nearby. The project provides family support such as childcare, household help and errands for cancer patients undergoing therapy and having children aged 0-13 years. ED Luxembourg currently provides funding for the project but the aim is for a government ministry to take this over in the future.

Sara Bojanić, from ED Serbia, described a “Pink Recipes” app called Stomacko (https://stomacko.com/pocetna) that she created that provides shopping advice and healthy recipes that may reduce cancer risk. Users can input how much money they wish to spend and how many people they are cooking for and the app suggests various recipes. As there was a lack of sources for reliable nutritional information, she relied on the Stanford University Healthcare Center for recipes for oncology patients. She reported that the recipes have been well received, and that there is potential expansion to include lifestyle issues. This follows the healthy lifestyles message of ED’s Breast Health Day.

A further highlight of this in-person conference was a special gala dinner to commemorate Susan Knox’s retirement and her more than two decades of dedication to Europa Donna during which she grew the organisation to its current reach and reputability. Susan retired from the CEO position in 2020 but continues in a policy advisor capacity.

The group and Susan Knox (right)

Ingrid Krücken

Acronym Finder

- ABC: advanced breast cancer
- AI: artificial intelligence
- BIG: Breast International Group
- CBT: cognitive behavioural therapy
- DCIS: ductal carcinoma in situ
- EBCC: European Breast Cancer Conference
- EBEP: Europe’s Beating Cancer Plan
- EBCTCC: Early Breast Cancer Trials Collaborative Group
- ECIB: European Commission Initiative on Breast Cancer
- ECIR: European Cancer Inequalities Registry
- EPAAC: European Partnership for Action Against Cancer
- ER: oestrogen receptor
- ESP (BWG): European Society of Pathology (Breast Working Group)
- ESSO: European Society of Surgical Oncology
- ET: endocrine therapy
- EUSOB: European Society of Breast Imaging
- EUSOMA: European Society of Breast Cancer Specialists
- GDG: Guidelines Development Group
- GRADE: Grading of Recommendations Assessment, Development and Evaluation
- IARC: International Agency for Research on Cancer
- IBCSG: International Breast Cancer Study Group
- IORT: intraoperative radiotherapy
- JRC: Joint Research Centre
- MBC: metastatic breast cancer
- MRI: magnetic resonance imaging
- MyPeBS: My Personal Breast Screening
- PICO: Population, Intervention, Comparison, Outcomes
- PREMS: patient-reported experience measures
- PROMS: patient-reported outcomes measures
- QASDG: Quality Assurance Scheme Development Group
- QoL: quality of life
- SLNB: sentinel lymph node biopsy
- TBCCT: Transforming Breast Cancer Together
- TNBC: triple-negative breast cancer
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