GOVERNMENT GAZETTE
A report by the Government Gazette Roundtable Unit

# BREAST CANCER REPORT

A multistakeholder collaboration

## Policy Roadmap to IMPROVE MANAGEMENT of the Cancer Burden in Europe

The Breast Cancer Report aims to inform a coherent policy approach to Breast Cancer prevention, control and treatment at European, regional and national levels. It provides policymakers with key information and recommendations.

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Our thanks are due to the following experts who have offered their expert insights to improve breast cancer treatment and management in Europe



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# The state we are in

1. Breast cancer is the most commonly occurring cancer in women and the second most common cancer overall, with over 2 million new cases in 2018.
2. According to GLOBOCAN 2018, breast cancer was by far the most common cancer among women in 2018 (24%), with 2.1 million people diagnosed and no fewer than 627,000 deaths worldwide, of which 98,755 in Europe.
3. It is the cancer that causes the most deaths in absolute terms. Breast cancer incidence rates are highest in the so-called developed regions (Australia, New Zealand, Europe and North America), but the world record is held by Belgium with 188 cases per 100,000 women.
4. The European Cancer Information System (ECIS) estimates that 404,920 women in Europe were diagnosed with breast cancer in 2018.

Despite significant advancements in treatment pathways, there are clear inequalities in access to rapid diagnosis and treatments across Europe. While there are several good breast cancer services across the continent, wide variations in healthcare systems have resulted in inequalities in multidisciplinary care. Metastasis is the leading cause of breast cancer deaths, killing half a million people per year across the world, yet quality of life and survival of patients living with metastatic breast cancer.

While many groups have worked to identify the remaining gaps in the provision of care, the goal of this report is to examine Europe's preparedness, assess current policy guidelines and schemes, explore new ways to improve prevention, diagnosis and treatment and discover practical solutions in order to build comprehensive prevention plans and ensure that effective measures, policies, and interventions would be in place.

The recommendations in this report are the result of desk research, includes expert editorials from industry leading stakeholders and have emerged from the conversations among the experts participating in the iCPS Breast Cancer Europe Roundtable 2018, with a view to making practical and actionable recommendations across the breast cancer care pathway, in order to facilitate and accelerate breast cancer research and improve treatments and quality of life for all women and men with breast cancer.

The call for action is addressed to policymakers at EU and national levels, healthcare professionals, academia, advocates, patients and members of the cardiac health community and required collective and collaborative approach across all member states.

## Call for action

**The European Commission and the European Parliament** should call on member states to make Specialised Breast Units (SBUs) mandatory by law.

**Europe should advocate an approach towards personalised medicine** and filter patients to improve treatment outcomes.

**It is crucial to have a more systematic and organised approach** towards screening of breast cancer.

**It is crucial that governments ensure the implementation of uniform guidelines** across member states and facilitate uniform and superior multidisciplinary care throughout Europe.

**The European Commission's Joint Research Centre** should stimulate strategies to gather and process continuous, complete, consistent and relevant data around the epidemiology, incidence and burden of breast cancer in Europe.


Our Breast Cancer Policy Recommendations come from the latest **iCPS Breast Cancer Roundtable** and from the conclusions of an independent panel of experts – including policymakers, breast cancer professionals, academics and industry leaders

# How can Europe manage breast cancer effectively?

Breast cancer is the second most common cancer killer in Europe with metastasis accounting for most of cancer deaths. However metastatic breast cancer is yet to receive the required attention from policymakers. With an aim to close the gap on metastatic breast cancer and to brainstorm ways to improve prevention, diagnosis and treatment of breast cancer in Europe, the International Centre for Parliamentary Studies (ICPS) recently brought together policymakers, breast cancer professionals, academics and industry leaders at a high-level policy roundtable in Brussels.

With more than 360,000 new cases per year, breast cancer is the most frequent cancer in the European Union, even when considering men and women together. It is the 2nd biggest killer after lung cancer with 91,000 deaths per year. Metastasis is the leading cause of breast cancer deaths, killing half a million people per year across the world, yet quality of life and survival of patients living with metastatic breast cancer remains vague. The exact number of people living with metastatic breast cancer (MBC) is currently unknown. Moreover, there is a gap between the public understanding and patient experience of MBC.

Despite significant advancements in treatment pathways, there are clear inequalities in access to rapid diagnosis and treatments across Europe. While there are several good breast cancer services across the continent, wide variations in healthcare systems have resulted in inequalities in multidisciplinary care. For instance, the average 5-years survival rate in Northern Europe is high at 85% compared to Eastern Europe where it is 75%.

For change to happen, we need regulatory measures that reduce the discrepancies in screening and diagnosis; improve treatment modalities and perk up the quality of life. In order to examine the ongoing policy challenges in managing breast cancer in Europe and explore strategies to improve treatment and care pathways, the International Centre for Parliamentary Studies recently convened a high-level policy roundtable on June 27, 2018 in Brussels. The goal of the roundtable was to examine the Europe's preparedness, assess current policy guidelines and schemes, explore new ways to improve prevention, diagnosis and treatment and discover practical solutions in order to build comprehensive prevention plans and



ensure that effective measures, policies, and interventions would be in place. Chaired by Prof Robert Mansel CBE, former president of the European Society of Breast Cancer Specialists (EUSOMA) and a world-renowned expert in breast cancer research, the **Breast Cancer Europe Roundtable 2018** brought together 40 breast cancer experts from more than 15 European countries to analyse the ongoing policy and clinical challenges in managing breast cancer patients, weigh up strategies to improve outcomes of metastatic patients and develop a roadmap for consistent, premium and multidisciplinary cancer care in Europe. Delegates included members of the European Parliament, senior representatives from the European Commission, breast cancer professionals, patient groups, academics, industry leaders and other key stakeholders.

Following a briefing about the descriptive epidemiology of breast cancer in Europe, the day's discussion commenced with policy updates from representatives of the European Commission and European Parliament, who presented an overview of the ongoing policy efforts in the European fight against breast cancer.

# Breast matters

Breast cancer is the most commonly occurring cancer in women and the second most common cancer overall, with over 2 million new cases in 2018. Breast cancer incidence rates are surprisingly high in the so-called developed regions such as Australia, New Zealand, Europe and North America, but the world record is held by Belgium with 188 cases per 100,000 women.

According to recent figures (GLOBOCAN 2018), breast cancer was by far the most common cancer among women in 2018 (24%), with 2.1 million people diagnosed and no fewer than 627,000 deaths (72 deaths per hour) worldwide, of which 98,755 in Europe.

The European Cancer Information System estimates that 404,920 women in Europe were diagnosed with breast cancer in 2018. Fortunately, mortality rates are falling thanks to the research conducted to date, which has led to more personalised treatments.

Though the overall risk of dying from breast cancer has been decreasing over the years; there is a wide variation in these mortality rates across several member states, particularly owing to significant disparities in treatment and care and late diagnosis associated with advanced stage cases of breast cancer.

According to the CONCORD study, five-year relative survival for breast cancer in Europe ranged from 57.9% and 62.9% in Slovakia and Poland, respectively, to 75.5%, 79.8%, and 82% in Germany, France, and Sweden with regional variations evident.

Rates of incidence are higher in western European countries, partly owing to availability to early detection through screening and care.

According to Europa Donna, the situation in Romania is the worse, and "exemplifies these disparities well". A study conducted by The Coalition for Women's Health indicates that Romania's average survival rate for patients with breast cancer is almost 10% lower than the EU's average, despite the lower incidence of the disease. According to the study, there would be three possible reasons for this worrying discrepancy: the lack of a national screening program, inadequate education and insufficient financial resources for breast cancer care.

Another statistic uncovered by the Coalition for Women's Health report is that for women over 65, the mortality due to breast cancer has increased by 28% in Romania in the period 1990-2013. Over the same time, the mortality rate in the EU has decreased by 14% in the same age range.

The lack of a viable national screening program has disadvantaged patients' health in Romania. Indeed, Romania ranks second to last in Europe for the percentage of women who have had a mammogram test in their lives.

## Reducing inefficiencies, improving outcomes

The group unanimously accepted that, while there have been tremendous effort to advance the management of early breast cancer, there is considerable room for improving treatment, care and support to patients with metastatic breast cancer. They presented the following key recommendations to support policy making.

**Delegates 2018:**

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## Policy recommendations

1. More public awareness among patients and policymakers should be generated about the European Commission initiative on Breast Cancer (ECIBC) which aims to harmonise the quality of the entire breast cancer care pathway across Europe;

2. While primary prevention of breast cancer is often quite complicated and predominantly biology-driven, national governments should increase social investment on prevention strategies and health-literacy efforts to increase awareness about risk factors;

3. Whilst several European countries boast of good breast centres, access to diagnosis and treatments have been quite varied across the continent. It is therefore crucial to have a more systematic and organised approach towards screening of breast cancer;

4. In the EU, 53% of breast cancer occurs among women who are out of the age range for screening (that is 50-70 in most countries). Therefore rapid diagnosis of symptomatic cancers which present at GP level should not be overlooked.

5. Despite the mushrooming of specialist breast centres across Europe, not all of them are fully accredited to provide superior multidisciplinary care to patients;

6. The European Commission and the European Parliament should call on member states to make Specialised Breast Units (SBUs) mandatory by law to increase patient outcomes and access to quality care;

7. It is important to ensure the issue of metastatic breast cancer is kept firmly on the European Parliament's agenda. Policymakers must recognise the unique needs of patients with metastatic disease in national cancer plans.

8. The European Commission's Joint Research Centre should develop clear guidelines on how to treat elderly women with metastatic breast cancer. Each multidisplinary team (MDT) should have trained specialists to treat geriatric patients and patients with the advanced disease;

9. EU and national policymakers should encourage and support collaboration between the research and clinical communities in the development of statistical and methodological tools that address the need for proper data analysis, while overcoming existing data challenges;

10. Limited data on MBC's distinctiveness from early breast cancer remains an issue which affects access to quality treatment and support services, thereby affecting patient outcomes. The European Commission's Joint Research Centre should stimulate strategies to gather and process continuous, complete, consistent and relevant data around the epidemiology, incidence and burden of breast cancer in Europe. Data collection and data monitoring has to be


made in an optimal setting in order to better inform the decision-making process;

11. Policymakers should develop strategies to increase access to quality breast care across Europe. Every patient should have the option to be treated in accredited breast centres;

12. Treatment efficacy doesn't differ so much between young and old, but treatment side effects may be more problematic in older individuals who generally have less physical reserves to cope with the side effects. Europe should encourage and provide greater access to geriatric assessment in the older cancer population as it has been shown to have major benefits;

13. There is a clear need to improve the presence of patient representatives as new treatment modalities cannot be built without understanding and addressing the requirements of breast cancer patients. Apart from this, there is also a need for universal policy to implement and bring the innovations to the patients;

14. As there is a need for a pan-European collaboration and widespread use of data to improve patient outcomes, policymakers should toughen the national capacity to collect, analyse and use representative data on the burden and trends of early and advanced breast cancers and its key risk factors;

15. Supportive and palliative care that alleviates symptoms, physical pain as well as psychological suffering is a human right for all breast cancer patients. In addition, every patient with an advanced disease should have an option to have a cancer nurse navigator;

16. Wide variations in healthcare systems have lead to inequality in access to care. It is crucial that governments ensure the implementation of uniform guidelines across member states and facilitate uniform and superior multidisciplinary care throughout Europe. More importantly, there should be no difference in quality assurance between private and public breast cancer centres;

17. Europe should advocate an approach towards personalised medicine and filter patients to improve treatment outcomes;

18. In order to improve quality of multidisciplinary care, policymakers should invest more on training programmes for surgical oncologists and specialist breast surgeons;

19. Finally, there is a crucial need to close the gaps between policy and clinical practices by sharing best practices between member states.

> It is important to ensure the issue of metastatic breast cancer is kept firmly on the European Parliament's agenda. Policymakers must recognise the unique needs of patients with metastatic disease .

## Where should Europe act?

In Italy, if a mother or wife wants to get a mammography regularly, at least every six months, she will have to pay up to €1,000 per year," says, Italian EFDD member Daniela Aiuto MEP, who is preparing a Parliament report on Breast Cancer. She noted that not all Italian families can afford these expenses nowadays. "This means that many women at risk of developing cancer give up prevention. It is here that we must act."

Daniela also highlighted the differences in prevention and treatment in different EU countries, saying women in northern Europe have more possibilities to have breast cancer diagnosed earlier and that this should be the same in all countries.

Although breast cancer can also develop in men, women are about 100 times more likely to be struck by it. In 2013 about 93,500 people died of breast cancer in the EU, 99% of which were women.

Over the years MEPs have raised awarreness of the issue in various ways, for example by adopting resolutions on breast cancer in 2003 and 2006.

In 2010 MEPs adopted a declaration to underline their support for the EU's commitment to fight breast cancer, by ensuring implementation of screening programmes and creation of specialist breast units and reliable data collection.

In 2015 MEPs adopted a written declaration on breast cancer in the EU, calling for the implementation of measures to fight this disease.

# *I have cancer but I want to work*

**Fatima CARDOSO** is the Director of Champalimaud Clinical Center and ***ABC Global Alliance***

Costs of cancer have an important impact on the global economy and encompass direct and indirect costs. The latter are often related to loss of productivity due to the inability to continue or return to work from many cancer patients and survivors. Cancer has an enormous impact in the personal, social and working relationships of people. To address the cancer burden in Europe, it is crucial to address disparities and harmonise standards for all Europeans. Many people want to continue working for financial security and to have a helpful distraction from their illness, and they should expect flexible support from their employers, as the effects of cancer treatment such as pain and fatigue can differ at various times. European and national politicians and policymakers need to implement consistent and flexible policies to enable cancer patients and cancer survivors to return to work.

**Scale of the issue**

One out of 8 to 10 women will have breast cancer in their lifetime, and the number of annual deaths will rise to more than 800,000 globally by 2030, about 43% more than the 560,000 deaths recorded in 2015. In Europe, there is a breast cancer diagnosis every 2.5 minutes and a death every 6.5 minutes. The latest Globocan 2018 data show that, in Europe, more than half a million women (and some men) are diagnosed with breast cancer annually and about 140,000 die from this disease each year.

About a third of those diagnosed with early stage breast cancer will later have a relapse/recurrence, even if diagnosed early and with access the best available therapies. It is unfortunately unknown how many advanced cancer patients currently exist in Europe since the majority of cancer registries do not record the occurrence of recurrence, but only incidence and mortality. This makes it harder to allocate resources and to implement the needed changes to address the needs of these patients. Recently, the European Network of Cancer Registries (ENCR), which focuses on finding ways to integrate data from Europe's cancer registries, started to be run at the European Commission's Joint Research Centre (JRC). It is crucial that the JRC includes mandatory collection of data on metastatic recurrences in breast and other cancers.

The ABC Global Alliance has made a thorough needs assessment of ABC patients and defined 10 priority goals to be addressed and achieved during the current decade: the ABC Global Charter.

These goals include doubling of median survival, increasing access to multidisciplinary care, include ABC in cancer registries, improving communications and information, and reducing stigma. Last but by no means least among the goals is "help patients with ABC continue to work by implementing legislation that protects their rights to work and ensure flexible and accommodating workplace environments", which given the rising incidence of breast cancer will mean more women (and some men) having to negotiate workplace arrangements.

**Working with employers and employees**

Work is an important part of one's identity, it fulfils the need for social structure and provides financial stability, a sense of normality and of purpose. But treatment and medication can cause fatigue, cognitive dysfunction, pain and other symptoms, and the path to getting better is not smooth; there are good days and weeks, but also bad times, and getting back to "normal" is often not possible. Cancer is life changing – physically and emotionally – it would be wrong to think otherwise.

Three important aspects to keep in mind are: 1) It is possible for most people with cancer, including those with advanced cancer, to continue to work; 2) Information must be given to employers and employees on what to expect during and after cancer treatment and how to manage at work. This means regular communication about the side-effects of treatment and having the flexibility to make adjustments for a gradual and successful return to work; 3) There must be a consistent EU-wide framework that supports all people with cancer who face discrimination in the workplace.

As an example, the UK Equality Act 2010, while not fully taken onboard by every employer, does a lot to protect cancer survivors against discrimination at work and to support their return to work, through for example, the requirement for employers to make reasonable workplace adjustments.

**Employment/return to work issues facing people with ABC**

The EU's Employment Equality Framework Directive 2000 is the legislative framework that

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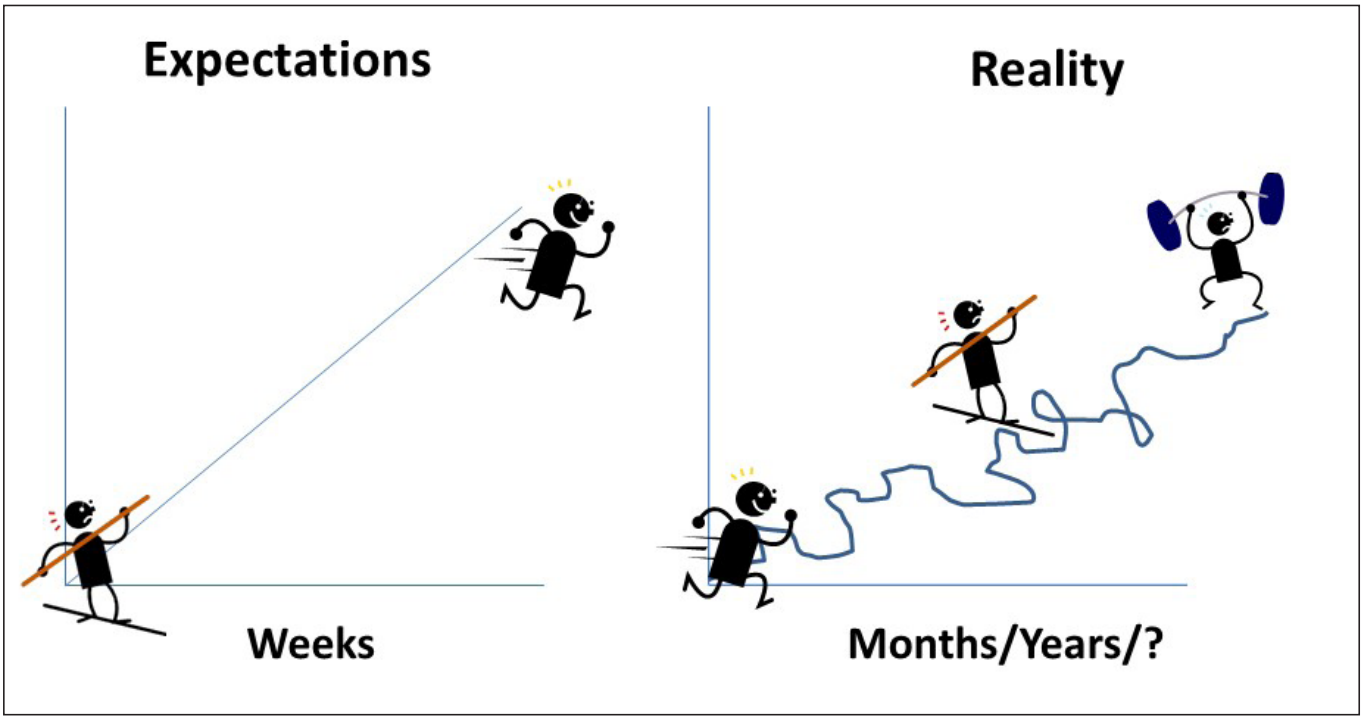


should protect people with both early and advanced cancer from discrimination. But it is an EU Directive and not an EU Regulation, and while it must go onto the statute books of the EU member states, each country has the flexibility to define what constitutes disability, and therefore whether or not cancer fits their definition.

Some countries, such as the Nordic countries, Netherlands, Ireland, France, Belgium and the UK do give cancer patients the ability to "register" as disabled and therefore to benefit from this legislation for their working rights, among other things. However, in many European countries, formal protection is either non-existent or the situation is legally ambiguous, and there are no data on how many cancer patients return to work or how easy they find it to do so. There are also big disparities in how countries help people to return to work after long-term illness – here the Scandinavian countries are good, offering cancer survivors a return to work plan.

Europa Donna, the European Breast Cancer Coalition, did a short survey of people with metastatic breast cancer about their experiences and support in their countries for employment and return to work. It found that, according to the survey respondents, a majority of the 35 countries represented do indeed have disability discrimination legislation that protects cancer patients, and some countries also have other legislation which protect people living with cancer from discrimination.

A majority also said there is information available on social security and welfare, and on leave of absence and return to work, and on working part time, although the latter is mostly dependent on the employer. Surveyed advocates and patient advocate also reported that pressure from employers and colleagues can discourage return to work, and there is stigma and lack of awareness of living and working with cancer.

There is some movement at EU level. A report from the European Parliament, "On pathways for the reintegration of workers recovering from injury and illness", (2017/2277 (INI)), now includes amendments on cancer. In May 2018, a group of MEPs led by Rory Palmer (UK) launched the EuropeanDying to Work campaign, which aims to protect terminally ill workers from dismissal;as it stands, there are no specific protections for terminally ill employees. Also, in 2018, MEP Deirdre Clune (Ireland) proposed a pilot project to the European Commission on collecting data on the number of people with metastatic cancer in the workplace, using breast cancer as a model; however, this project has not yet been funded. The aim of the project is to assist in designing better policies and service provision.

**Costs and value in cancer care**

There are big threats to achieving equitable care for breast cancer and other diseases – social inequalities, which are rising in Europe, and the impact of technology such as new drugs and imaging, which must be subject to guidelines and also must have anexperienced healthcare workforce that can deliver appropriate care. Breast cancer and colorectal cancer, due to their incidence, are the two cancers that particularly determine economic burden and whether policy response can control costs.

Economic impact is framed by direct healthcare costs and informal costs, balanced against productivity losses – and the figures are substantial. In Europe, total costs for breast cancer are over e14 billion, made up of 43% healthcare, 22% informal care, and 35% productivity lost to mortality and morbidity. Productivity loss of people unable to work is one of the biggest concerns for employers, although these figures also show the sheer cost that advanced cancer has on societies as people are lost to the disease. Several studies have shown that the percentage of indirect costs related to cancer is superior to the direct costs of treating the disease. Tackling the problem of loss of productivity would benefit substantially Europe and the World's economy.

**Reports and projects**

Previous published reports have highlighted the problem of loss of productivity angle. The Cancer in the Workplace report, published by the Economist Intelligence Unit in collaboration with Bristol-Myers Squibb in 2016, assessed the challenges that cancer poses for employers and reported that loss in productivity of cancer survivors who were unable to return to paid work in the UK was £5.3 billion in 2010. In a survey, productivity loss was ranked highest among the concerns of employers, followed by rising insurance premiums and the cost of days off sick. Notably, high among the concerns was the ability of managers to support employees with

cancer.The report also surveyed employees and, encouragingly, when asked whether they feel confident that their employer would support them during the period of illness and up to 1 year thereafter, around 75% of respondents said that they would be fairly confident or very confident. This figure is higher among respondents in large companies. However, in a more recent survey in the Netherlands, it was small, family owned businesses that offered the most support, ahead of larger companies and the public sector.

The Policy Roadmap on Addressing Metastatic Breast Cancerreport, published by a multi-stakeholder steering committee and Eli Lilly & Company, raised awareness on clinical, economic and societal burden of metastatic breast cancer and issued some recommendations, that include: 1) provide wider support systems and decision-making tools for metastatic breast cancer patients for coping with their diagnosis, handling their disease, managing their treatment's side-effects, and organising their lives to allow for minimal disruption; 2) the European Commission should use the European Pillar of Social Rights as a policy framework to initiate adequate measures to ensure member states provide patients and informal carers with employment regulations that sufficiently protect their work-life balance; 3) increase recognition of the role of informal carers and formalise their rights and access to available support systems.

The two Novartis-led projectsHere & Nowand My Time, Our Time have focused on the needs of ABC patients.

In 2013, 40% of women in Europe with advanced breast cancer who were surveyed were working and of those, 25% worked full-time; about 50% of patients had to change their work situation due to advanced breast cancer and 37% had to give up work temporarily or altogether. As a consequence, 56% of patients experienced a decline in household income as a result of being ill.

The road to a better normal: Breast cancer patients and survivors in the EU workforce is a recent report published by the Economist Intelligence Unit in collaboration with Pfizer and showed that societal and medical trends in Europe are intersecting to increase the number of breast cancer patients and survivors who are likely to want to work. In the past 15 years the proportion of European women aged 50-64 in employment has risen steadily, so that now a majority (59.6%) of that group are active in the labour force. The rate at which breast cancer patients and survivors return to work is highly uneven, suggesting substantial room for improvement. National return-to-work rates for breast cancer patients and survivors who were in a job at the time of diagnosis ranged from 43% in the Netherlands to 82% in France. Breast cancer and treatment side-effects make returning to work harder, but they are far from the only issues. Important non-medical barriers also impede a return to work, including lack of employer or colleague support, the extent to which work is physically demanding, and the level of education of the women involved. Such factors overlap to make specific populations vulnerable, particularly working-class women.

In addition to the summarized reports, it is important to consider that there are substantial numbers of self-employed women who do not have a formal workplace to return to, and face financial difficulties in particular. Younger women with breast cancer are likely to be most affected.

## Conclusion

Returning or maintaining a productive professional life is a crucial factor for cancer patients and cancer survivors. Reducing the costs associated with loss of productivity due to cancer would substantially decrease the economic burden of this disease in all countries.

The majority of cancer patients and survivors want and/or need to return to work but they face several limitations as a consequence of disease and treatments and need flexibility and understanding in their work environment. Some employers are willing to provide such flexibility but would need incentives and support.

The public sector should lead by example, but government employers are often the worst at supporting return to work. Organisations may respond better to incentives to adopt flexible policies rather than penalties and financial support is crucial to enabling flexibility for employers that find it hard to support unpredictable patterns of absence for cancer patients. Replacement income from welfare that switches in on days when an employee cannot work would help solve this.

Legislation protecting the right to return to work part time or with flexible hours, coupled with financial support and/or tax exemption for employers who apply that legislation, could be a solution to protect both employees and employers. Doing so, would substantial decrease the burden of cancer on each country's healthcare budget.

The 5-year prevalence (i.e. people who had a diagnosis of breast cancer in the last 5 years and are still alive) of breast cancer in Europe is over 2 million people. When considering all cancers, there are over 12 million people who had a diagnosis of cancer in the last 5 years and are still alive, the majority of whom are in their most productive years (40's, 50's and 60's). Europe cannot afford to lose this wealth of workforce.

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# *BRESSO sets high standards of breast surgery in Europe*

The European Society of Surgical Oncology (ESSO) is pleased to announce that a breast surgery specific working group has been recently established within the Society as a joint venture with EUROPADONNA (European Breast Cancer Coalition), EUSOMA (European Society of Breast cancer Specialists), the European School of Oncology (ESO), UEMS -European Board of Breast Surgery Qualification and the Oncoplastic Breast Surgery Consortium (OBSC).

BRESSO is the Breast Surgical Oncology Project Team working to promote accredited specialist breast surgical care for breast cancer patients and high risk women for breast cancer as a joint venture between key stakeholders.

It's vision is that all women affected by breast cancer should be treated by specialists trained and accredited in breast surgical oncology.

BRESSO is promoting the highest quality and most innovative, evidence based breast cancer care. It intends to develop the highest standards of breast surgical oncology in a multidisciplinary setting, for the benefits of our patients who should receive the best available care across Europe, no matter which country they live in.

BRESSO is supporting breast cancer patients to receive their treatment form accredited breast cancer surgeons within a multidisciplinary environment, benefiting from the expertise of highly skilled and trained surgical oncologists.

BRESSO aims to achieve this goal through a range of activities including:

- offering the leading platform for education and training in breast surgical oncology (courses, workshops, masterclasses, University linked Diplomas and Fellowships, Observerships) together with ESO, EUSOMA and other breast surgery organisations

- Europe-wide accreditation of specialist breast cancer surgeons (examination via UEMS delivered jointly by the UEMS, ESSO and EUSOMA, Fellowships adhering to the UEMS/ ESSO Breast Surgery Curriculum)

- Promote and initiate multi-national audits of standards in breast cancer surgical care, prospective data collection in collaboration with EUSOMA

- Facilitate availability and compliance with multidisciplinary guidelines and practice of quality cancer care, including the availability of oncoplastic breast surgery and reconstruction for all cancer patients across Europe

- Lead on and collaborate with policymakers on homogenisation of quality breast cancer management within Europe to achieve best long term outcomes and patient satisfaction

- Coordinate and bring together specialists involved in breast cancer surgical oncology and reconstructive surgery within a multidisciplinary environment

- Promote collaboration with core members of the multidisciplinary breast cancer care specialties

- Work closely with patient advocacy and support groups to provide them guidance in achieving the common goal of "highest quality cancer care for all European breast patients"

- Publishing position papers, guidelines, reviews

BRESSO intends to take on a leading role on the above topics at European level, with the clear intention to closely collaborate with key stakeholders in Europe, involved in breast surgery specialisation and accreditation (UEMS, EUSOMA, EUROPADONNA, ESO and other key organisations). Our goal is to raise and harmonise the quality and standards of breast surgical oncology across Europe.

**Current important assets of BRESSO:**

-Leading role in the UEMS/ FEBS European examination, jointly with EUSOMA

-EJSO, the Journal of Surgical Oncology with an increasing impact factor (3.688) and significant publications on breast topics

-Breast surgical network via ESSO membership

-Global and European Curriculum and Textbooks of Surgical Oncology and Breast Surgery

-Breast surgery and oncoplastic course portfolio with a expert faculty from across Europe

- University degrees in breast surgery and certification

The BRESSO Project Board is keen to collaborate and communicate with patient organisations and policymakers; establish strategic directions for the group and lobby for European recognition of breast cancer surgery as a surgical oncology subspecialty.

BRESSO will have a widely inclusive approach in creating a platform for representatives from leading educational, training, research and accreditation organisations and will thrive to achieve it's goals in a collaborative manner, keeping always in mind the best interests of our patients across Europe.

The group recently joined forces to promote accredited specialist breast surgical care for breast cancer patients and high risk women and our motto is that all women should be treated by specialists trained and certified in breast surgical oncology.

The article is authored by Dr Tibor Kovacs, Executive Director, European Society of Surgical Oncology (ESSO).

# Exercise and medicine for cancer survivors

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Advances in anti-cancer treatments mean that more people with cancer are living longer, but many people aren't actually living as well as they could be. Cancer survivors may experience considerable morbidity, increased risk of losing independence as they age, and significantly reduced quality of life. These effects also place unnecessary economic burden on the health care system. Addressing the detrimental effects of cancer and its treatment has been consistently identified as a central component of survivorship care.

Numerous systematic reviews and meta-analyses have concluded that regular exercise is a safe and effective intervention to counteract many of the adverse physical and psychological effects of cancer and its treatment.

Consistent evidence from epidemiological studies suggests that being more physically activite after a cancer diagnosis reduces the risk of cancer specific death and recurrence for certain cancer types. An increasing body of evidence has led international exercise organizations such as the American College of Sports Medicine (ACSM) and Exercise and Sports Science Australia (ESSA) to develop guidelines onexercise for cancer survivors. The ACSM guideline was published almost a decade ago with an update due in 2019. While the message for cancer survivors to be physically active and reduce sedentary behaviors such as prolonged sitting, is important, evidence supporting the exercise guidelines arises from interventions that are appropriately prescribed and monitored, and research continues to add insight to the precautions, adaptations, and optimal prescriptions for exercise in people with cancer. Appropriate exercise is an effective intervention for the long-term management of cancer and should be put forward as a critical element of survivorship care.

**Need for an exercise medicine model of care**

The current evidence of the various health benefits of exercise support a paradigm shift in oncological care.

Survivorship guidelines released by the American Society of Clinical Oncology specifies exercise as a core component of high quality survivorship care. Survivors have clearly indicated a desire to participate in appropriately designed and supervised exercise programs; however, no such services are routinely available for cancer survivors in most countries. The challenge is to develop a sustainable model of care that isaffordable and effective. Including exercise as an established and standard component of cancer survivorship may help to reduce some of the barriers to exercise, such as unequal access to evidence-based information, lack of access to exercise equipment, facilities, and exercise specialists.

Additionally, creating a standardised model of care for exercise in cancer survivorship will minimize the risk of missing the patients groups who are less likely to ask about exercise or to ask questions about their health in general.

Recent studies suggest that larger effects have been observed for interventions delivered at exercise facilities by appropriately qualified allied health professionals. Exercise should be prescribed and delivered under the direction of a qualified exercise physiologists, specialists or physiotherapistsin order to maximize safety and therapeutic effect.

These health professionals have expertise in understanding and identifying potential exercise contraindications and considerations and are able to use their clinical judgement in complex clinical scenarios. While not all people with cancer will require ongoing supervision, these practitioners will allow for exercise to be prescribed in line with evidence-based guidelines to help individuals with cancer meet exercise recommendations, which is important for the health, function, quality of life and, potentially, survival of people with cancer.

We now have enough evidence for the positive effects of exercise during and after treatment for breast cancer and it is time to take responsibility to make exercise as medicine available and part of treatment for women.

▶ The current evidence of the various health benefits of exercise support a paradigm shift in oncological care.

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# A plan to implement breast clinics across Europe

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It is estimated that 404,920 women will be diagnosed with breast cancer in 2018 in the European Union, while 98,755 women will die from the disease. Unfortunately the disease is here to stay. Indeed, its high incidence is in part related to modern life style, with delayed first pregnancies and fewer pregnancies depriving the mammary gland from full maturity and from enhanced "protection" against carcinogens.

While there is no doubt that progress has been achieved through earlier diagnosis and improved multidisciplinary treatment, one in four women will develop a recurrence and die from the disease, since breast cancer still remains incurable once it has spread to distant organs.

Hoping to eradicate undetectable micro-metastatic cancer cells (i.e., foci) in bones, lungs or in the liver, medical oncologists usually prescribe anticancer drugs to breast cancer patients deemed at risk of relapse. This is most often done after surgery and without any mean to assess whether the drugs wil lreally work for the individual patient.

In order to accelerate the development of more effective drugs against "micrometastases" clinical investigators have started to favour drug administration before surgery, a strategy called "neoadjuvant therapy",which evaluates how sensitive the primary breast tumor is to the drugs, with the hope that this sensitivity mimics the one of distant cancer foci.

After 15 years of conducting "neoadjuvant" clinical trials, one has learned that, for the most aggressive breast cancer subtypes (called "HER2-positive" if they overexpress the HER2 receptor or "triple negative" if they are devoid of both HER2 receptors and hormone receptors), not achieving a complete eradication of the primary tumour at surgery is associated with a significantly higher risk of cancer relapse (this risk being a smallpercentage only for women in "complete response").

Since, until recently no "salvage" drugs had been identified for poor responders to preoperative therapy, this "neoadjuvant"strategy has been mostly restricted– in routine clinical practice – to women for whom shrinkage of the breast tumour might allow for another wise impossible breast conservation "upfront".

In other words, today, most women with early breast cancer are offered drugs after surgery, implying a relatively smooth and easy coordination among breast cancer specialists along a treatment path where surgery comes first, followed by drug therapy (also called "adjuvant treatment") and radiotherapy.

Drastic changes in this sequence of interventions will take place tomorrow for women with HER2-positive and triple negative breast cancers considered at intermediate or high risk of relapse : indeed two landmark clinical trials – "Katherine" and "Create X" – have identified "salvage drugs" for women with residual invasive cancer in the breast following standard neoadjuvant therapy1,2.

The most robust of these trials, Katherine, which included 1400 women, showed an impressive gain of 11% in freedom of recurrence at 3 years follow-up for women receiving 14 postoperative courses of T-DM1 (an antibody-drug conjugate targeting the HER2 receptor) instead of additional treatment with trastuzumab (an anti-HER2 antibody) to complete 1 year of anti--HER2 therapy.

Create-X, on the other hand, has already impacted many national and European treatment guidelines for women with triple negative breast cancer not eradicated by preoperative drugs, since it showed a striking survival benefit for the oral cytotoxic drug capecitabine, when given in 8 postoperative cycles .

The implications of these two trials for optimal delivery of breast cancer care are very important : one in threewomen with an aggressive form of early breast cancer (HER2-positive or triple negative) will no longer be suitable for adjuvant drug therapy. Postponing surgery after initial drug therapy will become the new "must", as this will be the only way to identify those women for whom "salvage" drugs might be needed in order to optimise the chances of cure.

▲ Many European women continue to be treated in "satellite" breast clinics which do not reach a minimum of 150 breast cancer patients treated per year

The only caveat is that this different sequencing of treatment modalities requires a more complex coordination between breast cancer specialists, as well as a greater involvement of pathologists and imaging specialists. Some of the most critical steps here include 1) full molecular characterisation of the disease on a tru-cut biopsy (i.e. a small piece of tumour tissue); 2) "clipping" the breast cancer tumour, which might disappear under drug therapy; 3) characterising the status of axillary nodes with fine needle aspiration in case of suspicious clinical or sonographic features and 4) deciding on the most adequate type of surgical and radiotherapy treatment as a function of response to drug therapy.

Such a sophisticated multidisciplinary management is unlikely to be delivered with quality standards outside the framework of breast clinics.

Looking at the implementation status of breast clinics in the EU one gets very scared : only two countries have mandated them by law (Italy and the Czech Republic) and no country, so far, has linked reimbursement of care to the place where care is actually delivered.

As a result, many European women continue to be treated outside breast clinics or in loosely defined "satellite" breast clinics which do not reach a minimum of 150 breast cancer patients treated per year. This is also the situation in Belgium, my home country, with the additional worrisome observation of a paucity of breast clinics in the South compared to the North.

If politicians are serious about their desire to fight cancer – and in this case breast cancer – there is now a real urgency: breast clinics must be implemented taking into account geographical considerations and must form the basis for reimbursement of treatment interventions.

# Europa Donna supports transforming breast cancer care in Europe

**Susan KNOX** is CEO of ***EUROPA DONNA*** - The European Breast Cancer Coalition

There are currently 404,920 new cases of breast cancer in the EUeach year and 98,735 deaths (1). High quality early detection, followed by treatment in a specialist breast unit is still the best way to ensure living a full life after breast cancer.

As Europe's breast cancer advocacy organisation, Europa Donna (ED) seeks to ensure that all European women have information about, and access to, early detection through mammography screening programmes set up in accordance with the EU Guidelines and access to care and treatment in Specialist Breast Units as defined in EU guidelines.

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Our efforts over the last 20 years have been dedicated to making women aware of the services they should have the right to receive through consistent education, information and policy programmes. While much has been achieved many inequalities still exist between countries. See our websitewww.europadonna.org for policy and other initiatives undertaken.

Central to overcoming inequalities is training advocates from our member countries on current best practice so that they can take this information back to their countries and advocate for implementation locally.

Europa Donna has been conducting training programs for advocates since 2001. Each year advocates from all our member countries are invited to participate in advocacy training courses, advocacy leader conferences and most recently advocacy conferences for women with MBC(metastatic breast cancer).

In this way we ensure that advocates have the most up to date information on all aspects of early detection, breast cancer diagnosis, breast cancer surgery, imaging, and current treatments available for the disease. They are informed about evidence-based guidelines for mammography screening and how specialist breast units should be set up and conducted. Now this training includes a module on the ECIBC - European Commission Initiative on Breast Cancer. Europa Donna had been advocating for a Europe wide program such as this and has been following this initiative closely since its inception in 2013.

Susan Knox, ED's CEO, serves on the Guideline Development Group for the new EU Guidelines and Karen Benn, ED Deputy CEO, serves on QASDG Quality assurance scheme development group working on the QA scheme. Both serve as individual experts and not as ED representatives, in accordance with EC rules.

The GDG Guidelines Development Group, has recently published its first recommendations on screening which are available at http://ecibc.jrc.ec.europa.eu. Europa Donna is now actively promoting the implementation of these important EU guidelines and has begun by publishing "The Europa Donna Advocates Guide to the ECIBC". This is currently being used in all our training courses to ensure that advocates know the content of these new guidelines and understand how they were developed so that they can advocate for them effectively in their own countries.

The ECIBC provides concrete evidence-based recommendations that can and should be implemented by all countries.When it is completed the ECIBC will delineate the entire breast cancer pathway including diagnosis, treatment, follow up and rehabilitation etc thus providing an outline of what breast services should be provided to women across Europe.

The ECIBC will only be valuable if it gets implemented,so our main priority today is working toward that goal. We see that it is included in all of our training programs, conferences, information materials, as well as in key European scientific conferences such as EBCC of which we are a co-organiser with EORTC and EUSOMA. It is now imperative that all policy makers active both at the European level and the National level join together to ensure the implementation of the ECIBC in all countries.

Another key priority for advocates and for policy makers is ensuring that high quality research is carried out in Europe.

Europa Donna's role and involvement in research is broad and a number of our organisational goals are dedicated to breast cancer research.

Our involvement in the EU and international research agenda spans policy, education and direct involvement in research; this includes promoting relevant research trials that address important questions from the patient's point of view; being the informed link between professionals and prospective trial participants, representing

patients' needs and the consumer perspective, thereby adding balance; advocating for the dissemination of study results and availability of effective drugs across all countries.

In terms of policy, ED has always advocated for increased funding for all types of BC research, including ensuring that the EU Resolutions on Breast Cancer of 2003 and 2006, and Written Declarations on Breast Cancer of 2010 and 2015, include a commitment to high-quality, multi-institution, independent breast cancer research.

ED's extensive education and information programmes, including attending EU breast cancer conferences and meetings, ensures that ED's members, and patient advocates in its member countries, remain abreast of the latest scientific research and are trained to understand and participate actively and effectively on research committees.

Effective advocacy involvement means that Europa Donna advocates must be included from the outset of the research. Advocates are not there to "rubber stamp" trial protocols; they need time to study materials in advance, ask questions and participate actively in order to ensure credibility, independence, and provide real consumer perspective.

▲ Susan Knox, ED's CEO, serves on the Guideline Development Group for the new EU Guidelines and Karen Benn, ED Deputy CEO, serves on QASDG Quality assurance scheme development group working on the QA scheme. Both serve as individual experts and not as ED representatives, in accordance with EC rules.

To this end Europa Donna has conducted education programs for advocates and has published 3 booklets on research engagement that can be found on our website at https://www.europadonna.org/research/.

ED has been also been directly involved in the European research agenda for many years. We are the patient advocacy partner of BIG, the Breast International Group, which is a consortium of more than 50 institutions and academic breast cancer research groups headquartered in Brussels.

Through the BIG consortium we are currently serving on the steering committees of the MINDACT trial, the Olympia trial, and the AURORA research programme; in addition, ED representatives serve on the BIG Survivorship taskforce.

ED has also collaborated for many years with other EU consortia who receive EU funding, frequently through DG Research's programmes, including the Horizon 2020. We are currently engaged as consortium partners, or as external advisors, in 4 Horizon 2020 funded projects, PREFERABLE, BOUNCE, Mesi-stratand MyPEBS.

ED also has a representative on the Steering committee of EBCTCG - Early Breast Cancer Trialists' Collaborative Group, and on the ethics committee of IBCSG – International Breast Cancer Study Group; in addition, ED representatives are involved at an advisory level in the IBCSG's POSITIVE trial.

Europa Donna's involvement in clinical trials and studies can influence numerous areas including: ensuring that the research answers an important question of interest and use to patients and the public, leading to better and more user-friendly trial design, and ensuring that patient-oriented information, including consent forms, is presented in clear, comprehensible language, leading to a better understanding by potential trial participants.

Finally Europa Donna has a key role to play in explaining clinical trials and research in general to the public, to policy makers and to other stakeholders.

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The article is co-authored by Karen Benn, Deputy CEO of EUROPA DONNA.

# How to avoid recurrence and metastasis in women with hormone sensitive early breast cancer?

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Breast cancer is the most common cancer in women in Europe and worldwide (1). Once diagnosed, the prime goal of breast cancer treatment is to avoid the formation of metastasis which is the primary cause of death.

Breast cancer is not a singular disease but represents a diverse spectrum of biological features, prognoses, therapeutic options, and outcomes. Sub classification and drug treatment decisions depend on the presence or absence of receptors as these can bind hormones to enhance tumor growth or promote aggressiveness. Three prominent receptors may or may not be present: estrogen receptor (ER), progesterone receptor (PR), and HER (2).

Most breast cancers (two out of three) depend on estrogen for growth as they express ER. They can betreated with drugs that target the ER in order to block estrogen signaling, a concept that is referred to as anti-hormone (endocrine) therapy.

Breast cancer is not a singular disease but represents a diverse spectrum of biological features, prognoses, therapeutic options, and outcomes. Sub classification and drug treatment decisions depend on the presence or absence of receptors as these can bind hormones to enhance tumor growth or promote aggressiveness.

Two valid treatment options exist: Tamoxifen (TAM), a selective estrogen receptor modulator (SERM) that competes with estrogen for the binding to the ER to stop growth signaling, and Aromatase Inhibitors (AI) that block the enzyme aromatase to inhibit estrogen formation from androgens thereby decreasing womens' estrogen levels.Whereas TAM is the sole option for young women prior to menopause, women beyond menopause have a choice between TAM and AI. The benefits from anti-hormone therapy are impressive with long-term estrogendeprivation beinga mainstay in clinical breast oncology. However, there is a lack of drug efficacy in about one third of the treated patients that manifestsin recurrence, metastasis and premature death (2,3,4).

Given the high 5-year prevalence of breast cancer (1) with most women being on anti-hormone treatment, the predicted failure rate concerns several hundred thousands of women in Europe and probablymore than a million women worldwide. As of yet, it is not clear why some patients respond to a treatment and others don't.

Evidence from basic research (5,6) and clinical trials (3) demonstrated that therapeutic estrogen deprivation must occurfor 5 years in order to control the disease. 5-year treatment is needed as the mechanism of action is not immediatecytotoxicity but the reprogramming of micro metastatic cell(s) that remained in the woman's body after breast surgery so that these will no longer be susceptible to growth stimuli (5,6,8).

This is well in line with the clinically observed carry-over effect which prevents recurrence and reduces mortality during the decade after the actual treatment period (2,3,4). Thus, the completion of the 5-year treatment is strongly encouraged.

Yet, a considerable fraction of women is at constant risk for recurrence and premature death for as long as 20 years after stopping endocrine therapy (9).

Based on the observed beneficial effects of prolonged anti-hormonal treatment (10,11) current guidelines and opinion-based recommendations propagate prolonged therapy for up to 10 years particularly for women at high risk for relapse (large tumors, positive lymphnodes) (12,13,14).

Long-term every day drug intake however presents a challenge for the patients particularly when the drugs have unpleasant and severe side effects. Side effects of anti-hormonal drugs include menopausal symptoms such as hot flashes as well as muscle and bone aches which considerably lower women's quality of life, yetother reasons may also prevent womenfrom adhering to treatment (15,16).

Although the benefits of anti-hormone treatment scientifically and medically are indisputable, it is of no surprise that women frequently discontinue treatment prematurely.

Having gone through the distress of diagnosis, breast surgery, radiationand potentially chemotherapy, women usually get started on endocrine treatment but eventually stop using it,as they may feel well againand perceive their improved condition as being cured.

Unfortunately, women in Europe and worldwide are not sufficiently aware of that endocrine treatment is essential to prevent disease events/death in the future (9). In line with current guidelines and recommendations (13,14,15), it is of utmost importance

to raise the patients' awareness that long-term anti-hormone treatment is necessary to keep micro metastases at bay and stay alive.

While researchers are in charge to make anti-hormone treatment more efficient and safer it is to a large extent the patient's own authority to prolong her life by completing the planned treatment.

To raise this awareness must be the critical starting point for authorities and governments on their road map to reduce metastatic breast cancer in Europe.

To this end, patients must be empowered through knowledge provided across all countries and social classes in order to support their compliance to adhere to the planned duration of drug treatment. Removing critical barriers for getting patients to stick to therapy willhave enormous public health benefits.

Suffice to say that current costly developments towards improved drug treatment outcomeswill only serve their purpose provided the patient is willing to use the drug in the first place.

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Unfortunately, women in Europe and worldwide are not sufficiently aware of that endocrine treatment is essential to prevent disease events/death in the future. It is of utmost importance to raise the patients' awareness that long-term anti-hormone treatment is necessary to keep micro metastases at bay and stay alive.

# The importance of multidisciplinary approach and quality control in a Breast Centre

Breast Centre is the place where breast cancer is diagnosed and treated; it has to provide all services necessary from genetics to prevention, to the treatment of the primary tumour, to care of advanced disease, to palliation and survivorship and psycho-social support.

Since 2000, EUSOMA has published a milestone document on the requirements of a specialist Breast Centre, which has been pivotal for the setup of breast centres not only in Europe but also overseas and has been taken into consideration by national Authorities to define the organization of breast cancer management in their countries.

Despite this, as highlighted in the EBCC-10 Manifesto (EJC 72 (2017) 244-250), still too many European Countries have not deliberated on the management of Breast Cancer, missing the 2016 deadline for all patients in European Countries to access specialist multidisciplinary breast cancer units or centre.

Requirements are important referring tools and, as such, need to be regularly up-dated.

In this view, EUSOMA, with the endorsement of the European CanCer Care Organisation (ECCO) as part of the ECCO project "The Essential Requirements for Quality Cancer Care" - ERQCC, has finalised the updating of the paper "The requirements of a specialist Breast Centre" (EJC2013;49,3579-3587), with the contribution of European experts and representative of ECCO

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member discipline societies involved in the management of Breast Cancer Care.

This document will contain the updating of the existing Eusoma requirements taking into consideration changes in organization and care in the past 5 years and will also include sections on epidemiology, challenges in breast cancer and quality and audit processes.

Multidisciplinary approach, based on dedicated health professionals and quality control are two essential aspects of a specialist breast Centre,which has to offer harmonised quality care, regardless in which European country a person lives.

Multidisciplinary approach is based on the concept that not a single specialist but a group of specialised and dedicated experts will take shared decision on the diagnosis and care to be delivered to each patient.

Therefore, each Breast Centre must hold weekly multidisciplinary case management meeting to discuss diagnostic preoperative and postoperative cases and any other issue related to breast cancer patients, which need multidisciplinary discussion.

As highlighted in literature, this approach results into a great impact on patient survival.

A 2012 UK observational cohort study (Kesson EM et al Br. Med J 2012;344:e2178), evaluating the effects of multidisciplinary approach on nearly 14.000 women, showed that this approach was associated with a 18% lower mortality at 5 years.

Quality control is an essential tool to monitor the activity of the Breast Centre, the compliance with the adopted recommendations and protocols, the performance with regard to Quality Indicators.

It is necessary that each Breast Centre collects its data in a database and has within the team a data manager, i.e. a person qualified and trained to be responsible of the breast Centre data.

The data manager works under the supervision of the breast Centre clinical lead, organises audit meeting, monitors the trend of the Quality Indicators, keeps the team informed on that and takes part in the, at least yearly audit meeting, where all the team together discusses on the breast centres performance, on the need for any changes, improvements.

Again, with a multidisciplinary approach, the team identifies the necessary corrective actions, which might be not only clinical but also organizational or structural and therefore needs the involvement of the hospital management.

Quality control is very important not only for the single Breast Centre but also for the entire scientific community, because the benchmarking of the results of the different centres represent a helpful resource in the up-dating of national and international guidelines, in identifying new quality indicators or amendments of the existing ones.

Collecting data is essential for the scientific research at the breast centre, to allow to develop specific project and to publish local experience or to join national and international project.

There is evidence on the benefit of external audit, i.e. certification or accreditation, to better performance and outcomes, and this is true also for a breast centre.

Therefore, it is advised that a Breast Centre undergo a voluntary certification/accreditation process based on the offer at national or international level such as for example German Cancer Society and German Senology Society, National Accreditation program for Breast Centre (NAPBC) run by the American College of Surgeons, Breast Centre Certification, accredited scheme based on the Eusoma requirements and Quality Indicators.

The contribution of policymakers and politicians to make sure that all women in Europe are treated in specialist breast centres is fundamental.

Only joint forces from health professionals, patients' advocates, policymakers and politicians can ensure that breast cancer patients have access to specialist breast centres in any European countries.


# ECIBC commits to ensure effective and safe breast services across Europe

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Breast cancer is the most common cancer among women in the European Union. Data from the European Cancer Information System (ECIS),managed by the European Commission's Joint Research Centre (JRC), indicate that more than 400,000 new cases were diagnosed in 2018.

Indicators of quality of care and patient experience and of accessibility to breast cancer centres were showing discrepancies among member states and within member states; this discrepancies push the Commission to launch the ECIBC with the view to tackle these inequalities through updating the previous European Guidelines for quality assurance in breast cancer screening and diagnosis, reflecting the latest scientific developments with the aim to improve and harmonise the quality of breast cancer services and to overcome inequalities in accessing careacross Europe. The ECIBC is operated by the EC-JRC under the umbrella of collaboration with the EC Directorate General for Health and Food Safety (DG SANTE).

It involves today 35 participating countries across Europe. In addition to representations of all EU Member States, also Island, Macedonia, Montenegro, Norway, Serbia, Switzerland and Turkey are collaborating on the European Commission's initiative.

The ECIBC objectives are achieved through the development of: (1) new European breast guidelines on screening and diagnosis, and (2) of an associated quality assurance scheme with particular attention on the patients' needs, using the latest scientific evidence available. The ECIBC covers the entire breast cancer care pathway, from screening of asymptomatic women to diagnosis, treatment, rehabilitation, management of recurrence and palliative care.

The European Breast Guidelines are developed using Grading of Recommendations Assessment, Development, and Evaluation (GRADE) methodology.

The GRADE Evidence-to-Decision framework grants full transparency about the process followed for each ECIBC recommendation.

These recommendations focus on many crucial aspects of breast screening and diagnosis, for example: when and how often women should attend mammography screening, which technology should be used, how women should be invited to ensure high population coverage, how results should be communicated, how more vulnerable parts of populations should be addressed and which diagnostic methods should be used. ECIBC's recommendations aim to guide healthcare professionals and policymakers to plan, organise, and deliver effective and equitable breast cancer services. At the same time, the recommendations can also help women to be better informed on their care options.

The ECIBC recommendations are being published online as they are progressively developed. Guidelines developers and screening programmes organisers of several countrieshave already expressed their interest to either adopt and/or adapt ECIBC recommendations for their own National or regional programmes , such asfrom countries of the European Union (Bulgaria, Czech Republic, Greece, Estonia, Italy, Malta, Romania, Slovakia, Spain, United Kingdom) as well as from Armenia, Bahrain, Brazil, China and Macedonia.

The ECIBC Quality Assurance (QA) Scheme will, once finalised in 2020, cover the entire breast cancer care pathway, from screening to palliative care. The QA scheme sets quality criteria needed to guarantee that breast cancer care is effective and safe when implemented in breast services.

The ECIBC working groups include health care professionals as well as patients and patient advocates, such as Europa Donna – The European Breast Cancer Coalition, who participate in every phase of the discussion and development of both the guidelines and the quality assurance scheme.

Moreover, several calls for feedback were posted on the ECIBC website in the recent years which outcome was considered during the activities of the various working groups to ensure that the various stakeholder needs are properly considered during the development of ECIBC.

The implementation of the ECIBC scheme into national contexts is voluntary. Therefore, the European Commission initiative has been developed in a flexible and adaptable way to allow local guideline developers to make best use of ECIBC by incorporating individual recommendations into local programmes or adopting ECIBC in total in breast services.

2019 will be an important year for ECIBC: the work on recommendations development will be finalised and the ECIBC will experience the first practical applications of the QA scheme to be ready for the final roll-out of the ECIBC scheme in 2020.