

An illustration of four hands, two on the left and two on the right, cupping a globe. The hands are rendered in a dark purple color, and the globe is a lighter shade of purple. The background is a gradient of purple, transitioning from a darker shade at the top to a lighter shade at the bottom.

TRANSFORMING BREAST CANCER TOGETHER

**WHITE PAPER ON A NEW COLLABORATIVE INITIATIVE
TO IMPROVE BREAST CANCER PREVENTION,
DIAGNOSIS AND CARE ACROSS EUROPE**



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1. BACKGROUND

The 'Transforming Breast Cancer Together' initiative was established when influential policy makers and organizations strongly committed to cancer care began to collaborate following a poignant cancer care event on 8 November 2017, hosted by Elena Gentile (S&D) and Lieve Wierinck (ALDE), Members of the European Parliament (MEPs). The ultimate goal of this initiative is to reduce the societal impact of breast cancer by elevating it as a health policy priority in order to improve breast cancer prevention, diagnosis and care across Europe. The initiative is driven by a group that currently includes the following stakeholders:

- MEP Elena Gentile (S&D), MEP Lieve Wierinck (ALDE) and MEP Cristian Silviu Buşoi (EPP)
- Eli Lilly & Co (Eli Lilly & Co joined the group at a later stage)
- European Society of Surgical Oncology (ESSO)
- Europa Donna – The European Breast Cancer Coalition
- European Cancer Patient Coalition (ECPC)
- European School of Oncology (ESO) and ABC Global Alliance
- European Society of Breast Cancer Specialists (EUSOMA)
- GE Healthcare
- Helsinn
- Novartis
- Working With Cancer

Throughout 2018 the group executed a number of awareness building activities under the concept of a "String of Pearls", where each activity aimed at raising awareness of pressing issues concerning breast cancer represents a new 'pearl' on the string. Indeed, a number of initiatives commenced to address a multitude of issues related to breast cancer prevention and care, including the need to address the differences in cancer care across European Member States, the importance of diagnosing and treating breast cancer in the early stages, the need for support in the workplace for patients suffering from breast cancer, and the unique needs of patients with advanced breast cancer.

Some of the concrete outcomes of the 'Transforming Breast Cancer Together' initiative include:

- The direct and regular involvement of 3 Members of the European Parliament in defining the strategy and activities of the campaign, plus the involvement of other stakeholders in the groups outreach, including the European Commissioner for Health and EU Member States' Ministers of Health.
- Patient empowerment through various activities which have directly or indirectly targeted patients, such as:
 - The dissemination of the "Call to Action" to patient advocates in 47 countries by Europa Donna, as well as by ECPC and other members of the campaign.
 - An interview by Working With Cancer of MEP Lieve Wierinck about her experience with cancer and her political commitment to improve cancer care.
- Two op-eds written by supporting MEPs published in both EU outlets and national publications aimed at increasing general public awareness of the challenges of breast cancer and existing disparities in Europe.
- Addressing the critical need for implementation of Breast Cancer Units across Europe and the standardization in the management of patients through specialized breast cancer specialists. Indeed, the group has been raising awareness about a European accreditation in Breast Cancer Surgery that ESO, ESSO, EUSOMA and Europa Donna have started to develop in order to standardize breast cancer surgical treatments regardless of the country in which the patient is treated.

In light of the above, this white paper intends to provide an up-to-date overview of the health and economic burden of breast cancer in Europe, and present breast cancer not only as a population health problem, but also as a socio-economic problem, as it underlines that European healthcare systems are still heterogeneous with stark inequalities existing in access, quality and patient outcomes. Lastly, it will review recent EU level policy initiatives related to breast cancer, as it stresses that the EU has played an important role in tackling breast cancer and that it should continue to provide its support on breast cancer diagnosis and care. Indeed, the white paper comes at a crucial time for the EU, with European elections coming up in May 2019 and policymakers about to discuss the competences, the scope and the priorities of the European Union.



2. BREAST CANCER IN THE EU: OVERVIEW OF THE HEALTH AND ECONOMIC BURDEN FOR SOCIETY

Cancer, in all its forms, is the second most common cause of mortality in Europe, after cardiovascular diseases¹, making it a formidable societal issue. Despite significant improvements in screening, diagnosing and treating the disease, cancer continues to represent a heavy burden on European society². While cancer can be considered a 'silver tsunami' - predicted to increase further, considering the ageing of the European population³ - it is also increasingly affecting a younger demographic, as is the case for breast cancer, where about 20% of all breast cancer cases diagnosed in Europe are in patients under 50 years old⁴.

Breast cancer has a profound impact on European society as a whole as it is the most common cancer in Europe.⁵ In addition, breast cancer is the leading cause of cancer death among women, causing 94 300 deaths in 2015 and accounting for 16% of all female cancer deaths⁶. European women have a 1 in 8 chance of developing breast cancer.⁷ Clearly, breast cancer is a pressing public health issue.

It should be emphasized that this situation varies across Europe and geographical patterns, and stark differences between regions are emerging. The incidence rate is higher in Northern, Southern and Western Europe - where they are amongst the highest in the world⁸ - than in Eastern Europe⁹. However, while we find the highest rates of new cases of breast cancer in Northern and Western Europe, it is in Eastern Europe where we find the highest death rates from breast cancer. This concerning situation illustrates the large health inequities that currently exist across and within Member States¹⁰. Survival rates of patients with breast cancer have increased in most countries across Europe, but remain lower in Estonia, Poland, the Czech Republic, the UK and Ireland, according to the Organization for Economic Co-operation and Development (OECD)¹¹, looking at data from 2008-2013. While Eastern European countries demonstrate higher death rates from cancer, the data does not suggest a clear east-west pattern, as there are a number of northern and western European countries with higher mortality than their immediate neighbours. For example, whilst mortality from breast cancer has fallen in most EU countries since 2000, particularly strong reductions occurred in Denmark and Malta. In Croatia, on the other hand, breast cancer mortality rate has increased since 2000 and the country now has the highest mortality rates of all EU countries¹². Differences in incidence and mortality rates may reflect the availability of accurate statistics or collection methods. There are, for example, countries (such as Greece) where there are no cancer registries, making it difficult to assess geographical patterns or to draw conclusions within and across countries¹³.

In terms of the economic burden of breast cancer, a study found that the cost of lung, breast, colorectal, and prostate cancers in the EU in 2009 was €55.3 billion i.e., 44% of the total economic cost of cancer in the EU.¹⁴ Lung cancer was said to have the highest economic cost (€18.8 billion, 15% of overall cancer costs), followed by breast cancer (€15.0 billion, 12%). Breast cancers accounted for the highest healthcare costs (€6.73 billion; 13% of all cancer-related healthcare).¹⁵

In Europe, higher socioeconomic status has been linked to an elevated rate of breast cancer compared with those in lower socioeconomic status¹⁶. These differences are not necessarily based on socioeconomic status itself but rather due to differences in risk factors such as lifestyle, birth control and hormone replacement therapy (HRT) usage, and reproductive factors such as older age at first pregnancy. However, women of a higher socioeconomic status have a lower rate of death from breast cancer than do those from a lower socioeconomic status. This could be due to having greater access to mammography screening compared with women of a lower socioeconomic status.¹⁷

1 OECD/EU (2018), Health at a Glance: Europe 2018: State of Health in the EU Cycle, OECD Publishing, Paris.

https://doi.org/10.1787/health_glance_eur-2018-en

2 Global Burden of Disease Collaborative Network, Global Burden of Disease Study 2016 (GBD 2016) Cancer Incidence, Mortality, Years of Life Lost, Years Lived with Disability, and Disability-Adjusted Life Years 1990-2016, Institute for Health Metrics and Evaluation, 2018

3 Ibid.

4 Ferlay J, et al. (2018). Global Cancer Observatory: Cancer Today. Lyon, France: International Agency for Research on Cancer. Available from: <https://gco.iarc.fr/today>, accessed [30 October 2018].

5 Ferlay, J. et al. "Cancer incidence and mortality patterns in Europe: Estimates for 40 countries and 25 major cancers in 2018" European Journal of Cancer, Volume 103, 356 - 387

6 OECD/EU (2018), Health at a Glance: Europe 2018: State of Health in the EU Cycle, OECD Publishing, Paris.

7 European Commission Initiative on Breast Cancer (2018) "Recommendations from European Breast Guidelines" Accessible at: <http://ecibc.jrc.ec.europa.eu/recommendations/>

8 Bray, et. al. (2018) 'Global Cancer Statistics 2018: GLOBOCAN Estimates of Incidence and Mortality Worldwide for 36 Cancers in 185 Countries' CA CANCER J CLIN 2018; 0:1-31

9 Abbott, P. (2013) "The Invisible Woman: Unveiling the impact of advanced breast cancer on women, families, society and the economy across Europe", Here and Now Report, Available at: <https://www.werehereandnow.com/files/here-and-now-report.pdf>

10 European Institute of Women's Health (2017) "Policy Brief: Women and Breast Cancer in the EU - a life Course Approach". Available at: <https://eurohealth.ie/women-and-breast-cancer-in-the-eu-a-life-course-approach/>

11 OECD/EU (2016) Health at a Glance: Europe 2016 - State of Health in the EU Cycle, OECD Publishing, Paris.

12 OECD/EU (2018), Health at a Glance: Europe 2018: State of Health in the EU Cycle, OECD Publishing, Paris.

13 OECD/EU (2016) Health at a Glance: Europe 2016 - State of Health in the EU Cycle, OECD Publishing, Paris.

14 Ramon Luengo-Fernandez et al (2013) "Economic burden of cancer across the European Union: a population-based cost analysis" Lancet Oncology, 14 (12), pp.1165-1174

15 Ibid.

16 European Institute of Women's Health (2017) "Policy Brief: Women and Breast Cancer in the EU - a life Course Approach". Available at: <https://eurohealth.ie/women-and-breast-cancer-in-the-eu-a-life-course-approach/>

17 Ibid.



Morbidity and mortality from breast cancer have profound social and economic impacts. For working women, breast cancer can have a significant and sometimes devastating impact on their careers through shortened employment, fewer working hours, and loss of income (see section 8). In addition, many households depend on women aged 50+ for social and economic support. A significant proportion of these women look after their own children or their grandchildren, or both¹⁸. Many also care for elderly and disabled relatives and do voluntary work in the community. If they are unable to do some or all of this 'grey economy' work, then replacing their unpaid labour has an estimated replacement cost of around €8,767 per year for each woman, a total of €876.5 billion from 11 European countries¹⁹.

For healthcare systems and all stakeholders, noticeably policymakers, it is important to understand the profound social and economic impact of breast cancer.

3. INEQUALITIES IN BREAST CANCER SCREENING AND DIAGNOSIS IN EUROPE

Across Europe there remain significant disparities in the incidence of breast cancer and outcomes of care. The overall risk of dying is decreasing, in line with improvements in screening, diagnosis and treatment; however, variation in the rate of reduction exists according to stage of disease and country²⁰. The CONCORD study demonstrated that 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.²¹ Such trends have been established in other studies, notably the Eurocare 5 report and The International Cancer Benchmarking Partnership Study.²² Factors implicated include late diagnosis associated with advanced stage at presentation as well as variation in treatment.²³

In general, there are major difference across the individual EU member states in breast cancer screening and care, which result in some countries having much lower survival rates than others.²⁴ The higher incidence rate in western European countries compared to those in the south can be at least partly, explained by early detection through screening services and by lifestyle issues in western countries.²⁵

The situation in Romania with regards to breast cancer exemplifies these disparities well. According to a study conducted by The Coalition for Women's Health^{26,27}, 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.²⁸ According to the study, there would be three possible reasons for this worrying discrepancy: the lack of a national screening program (the first pilot was launched in 2018²⁹), inadequate education about women's health, and insufficient financial resources for breast cancer care. Another worrying 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.³⁰ This issue also affects countries such as Greece and Slovakia, two countries that also lack a national screening program.

18 Abbott, P. (2013) "The Invisible Woman: Unveiling the impact of advanced breast cancer on women, families, society and the economy across Europe", Here and Now Report, Available: <https://www.wearehereandnow.com/files/here-and-now-report.pdf>

19 Ibid.

20 Ferlay, J. et al. (2012) "Cancer incidence and mortality patterns in Europe: estimates for 40 countries in 2012". Eur J Cancer 2013;49:1374-403

21 Coleman, M.P. et. al. (2008) "Cancer survival in five continents: a worldwide population-based study (CONCORD)". Lancet Oncology 2008;9:730-56.

22 De Angelis, R. et al. (2014) "Cancer survival in Europe 1999-2007 by country and age: results of EUROCARE-5—a population-based study" Lancet Oncology 2014;15:23-34.

23 Coleman M.P. et. Al. (2011) "Cancer survival in Australia, Canada, Denmark, Norway, Sweden, and the UK, 1995-2007 (the International Cancer Benchmarking Partnership): an analysis of population-based cancer registry data". Lancet 377:127-38

24 Buşoi, C. S. (2018) Time to address the EU's inequalities in breast cancer diagnosis and care Available: <https://www.euractiv.com/section/health-consumers/opinion/time-to-address-the-eus-inequalities-in-breast-cancer-diagnosis-and-care/>

25 Abbott, P. (2013) "The Invisible Woman: Unveiling the impact of advanced breast cancer on women, families, society and the economy across Europe", Here and Now Report, Available: <https://www.wearehereandnow.com/files/here-and-now-report.pdf>

26 The Coalition for Women's Health & Roche Romania (2017) POVARA CANCERULUI DE SÂN ÎN ROMÂNIA. BENEFICIILE INVESTIȚIEI ÎNTR-UN PROGRAM DE SCREENING PENTRU CANCERUL DE SÂN Available: https://www.roche.ro/content/dam/rochexx/roche-ro/roche_romania/ro_RO/files/2017/pr-171101-studiu%20Deloitte-povara-cancerului-de-san.pdf

27 ISRA Center, The Coalition for Women's Health & Roche Romania (2016) Female Oncologic Diseases in Romania Available: <https://www.think-pink.be/Portals/1/dtxArt/blok-document/bestand/db638d6e-2604-4838-b83e-c30010d0e138.pdf>

28 International Agency for Research on Cancer (2018) "Cancer today" Available at: <http://gco.iarc.fr/today/home>

29 Marica, I. (2017) "Romania to use EU funds for first breast cancer screening program" published in romania-insider.com. Available: <https://www.romania-insider.com/breast-cancer-screening-program/>

30 Buşoi, C. S. (2018) Time to address the EU's inequalities in breast cancer diagnosis and care Available: <https://www.euractiv.com/section/health-consumers/opinion/time-to-address-the-eus-inequalities-in-breast-cancer-diagnosis-and-care/>



These inequalities demand that European and national decision-makers assign the highest priority to initiate the much-needed measures necessary to see a consistent and continued improvement in survival rates. This priority action will see the EU make progress in the fight against breast cancer. Patients with breast cancer will have improved outcomes and a higher quality of life, their families will benefit as well, and with sustained action the overall societal impact of this disease will lessen.

4. EVOLUTION OF BREAST CANCER TREATMENT PARADIGM

REDEFINING CANCER - KEY MILESTONES AND INNOVATIONS

Cancer research, including on breast cancer, is undergoing a continuous and remarkable revolution, with exciting discoveries frequently in the news. For several types of cancer, a paradigm shift has appeared in the past 10-15 years, with survival rates extended far beyond what was once considered the norm (notably HER-2 breast cancer).³¹ A recent novel and comprehensive study³² evaluated the therapeutic value of all (62) new cancer medicines approved by the US Food & Drug Administration (FDA) and the European Medicines Agency (EMA) between 2003 and 2013. The results of this study revealed an extension in overall survival (OS) of 3.43 months (mean) for all cancer drugs approved in this time period over the survival associated with treatments available in 2003. While modest, even minor improvements in survival can have an effect of reducing mortality at the population level. Importantly, the mean improvement in OS for new breast cancer treatments was 8.48 months (mean), substantially higher than that seen for the group mean, and far beyond the 3-month threshold that regulators deem to be clinically meaningful. This substantial improvement offers hope to patients with breast cancer and to society, and suggests that innovation in the oncology drug market can bring real value to patients and society.

While new research on cancer provides hope for the development of new treatments, it also adds a layer of complexity. For instance, historically, “breast cancer” was understood to be a single disease until Perou et al. (2000) classified it into 4 distinct subtypes.³³ Today further research – yet to be validated – suggests that there could be at least ten distinct molecular subtypes of breast cancer that could each require a different treatment approach.³⁴

IMPORTANCE OF INVESTMENTS IN PREVENTION, DETECTION, TREATMENT AND MANAGEMENT OF BREAST CANCER

Breast cancer is a potentially curable disease if diagnosed and treated at an early stage; breast cancer cases diagnosed at an early stage (Stage I/II) have a better prognosis (5-year survival rate of 85%-98%) than patients diagnosed with advanced breast cancer (Stage III/IV) (5-year survival rate of 30%-70%). To date, there are still many European women who are diagnosed too late due to inadequate participation in screening programs; at the same time, the availability of therapeutic solutions is limited, in particular for patients that are diagnosed in a late stage.³⁵

To gain the maximum improvements in breast cancer and metastatic breast cancer survival rates, patients must have access to mammography to enable early diagnosis and early treatment around the European Union. Over time success will lead to reduced health care costs and relieve the economic burden placed on national governments.³⁶

Due to its high incidence, breast cancer has the highest health care costs (€6.73 billion)³⁷ of all cancer-related health care costs in Europe, but that figure could be significantly reduced by treating the disease in its earliest stages. Research repeatedly shows that treatment costs are substantially lower in the earlier stages of breast cancer: in France, treating patients with early-stage localized disease is €20,000 cheaper than treating patients in the advanced stages of breast cancer. In Belgium, the average per-patient cost during a 6-year period is €19,827 for patients with stage I disease versus €35,201 for patients with stage IV disease (a €15,000 difference per patient each year)³⁸.

31 Drakaki, A., Hurvitz, S.A. (2015) “HER2-Positive Breast Cancer: Update on New and Emerging Agents” *Amj Hem Onc.* 2015, (11), 4

32 Salas-Vega S., et. al. (2017) “Assessment of Overall Survival, Quality of Life, and Safety Benefits Associated With New Cancer Medicines” *JAMA Oncol.* 2017 Mar 1;3(3):382-39

33 Perou CM, et. al. (2000) “Molecular portraits of human breast tumours.” *Nature.* 2000 Aug 17; 406(6797):747-52

34 Curtis C et al. (2012) “The genomic and transcriptomic architecture of 2,000 breast tumours reveals novel subgroups” *Nature* Apr 18;486(7403):346-52.

35 Di Leo, A. et.al. (2015) “New approaches for improving outcomes in breast cancer in Europe” *Breast*, 24(4), 321-330.

36 Ibid.

37 Gentile, E and Wierinck, L. (2018). On breast cancer our work is far from over Available: <https://euobserver.com/opinion/141126>

38 Ibid.



A review of the EU-28, and Iceland and Norway, from 2005 to 2015 found a strong correlation between per capita spending on cancer and improved survival³⁹. This association was found to be especially strong for breast cancer and colorectal cancer, significantly, two of the cancers with the highest absolute numbers of deaths in Europe and two of the top three cancers that impact productivity in terms of years of potential life lost (YPLL)⁴⁰.

The potential for further significant scientific advances in the prevention, detection, treatment and management of breast cancer is high, building on the findings from research in recent years. However, this will require increased funding of research, increased cross-disciplinary collaboration, improved clinical trial methodologies and the communication of and translation of research findings into clinical practice.⁴¹ In Europe, on average, only 5% of cancer research funding is spent on investigating metastasis even though 90% of cancer deaths are due to it.⁴²

5. THE PSYCHOLOGICAL IMPACT OF BREAST CANCER

Receiving a diagnosis of breast cancer can be one of the most distressing and devastating events women ever experience. Women may not know where to turn for help as often the urgent demands of treatment may impel health care providers to focus on physical aspects of care. However, addressing the physical demands of the disease is just one part of a comprehensive treatment plan that must also include support for patients' psychological needs.

Patients who receive a cancer diagnosis often experience various levels of stress, anxiety, and fear related to uncertainty about what the future holds. Such emotions have a significant impact upon psychological health. Treatments that drain time and energy can make it hard to enjoy socializing, favorite activities and important family-related tasks. Many patients experience difficult changes related to sexual function, child bearing and for some, early menopause. Breast cancer diagnoses that require drastic surgical steps, such as a mastectomy, can have a prolonged impact on a patient's body image and sense of self. Navigating the logistical and financial aspects of treatment, whether addressing complicated insurance and payment questions or making difficult decisions regarding various treatment plans, can additionally contribute to stress and overwhelm patients as they map the course of action that best suits their lifestyle and needs. A breast cancer diagnosis can also lead to more severe problems such as depression, which can make it more difficult for them to adjust, make the most of treatment, and utilize sources of support.

The link between physical and psychological health, particularly with cancer, is well documented. According to one meta-analysis⁴³, mortality rates were found to be up to 25% higher in patients experiencing depressive symptoms and up to 39% higher in patients who had been diagnosed with minor or major depression.

It is essential to equip providers with the knowledge and skills that address patients' needs beyond the physical and to embrace the need for psychological care as an integral part of a comprehensive treatment plan.

39 Jönsson, B. et. al. (2016) "Comparator report on patient access to cancer medicines in Europe revisited" IHE Report 2016:4. Available at: https://www.efpia.eu/media/412110/ihe-report-2016_4_.pdf

40 Ibid.

41 Mayer, M. (1998). Advanced breast cancer. 2nd ed. Beijing: O'Reilly

42 Steeg P., and Sleeman J., (2010). "Cancer metastasis as a therapeutic target". European Journal Cancer. 46: 1177-1180.

43 Satin, J., Linden, W. and Phillips, M. (2009). Depression as a predictor of disease progression and mortality in cancer patients. Cancer, 115(22), 5349-5361.



6. UNMET NEEDS: THE EUROPEAN PERSPECTIVE

Despite advances in the treatment of breast cancer, as many as one in three patients diagnosed with early breast cancer go on to develop advanced breast cancer⁴⁴ and a small yet consistent percentage of women (about 10%)⁴⁵, in Western Europe, have advanced-stage disease at diagnosis. This rate is much higher in low-middle income countries such as some Eastern European countries.⁴⁶

Breast cancer in advanced stages is associated with low survival rates across Europe, and there is not enough therapeutic support for those who are living with the disease⁴⁷.

To win the fight to improve cancer care across Europe, policymakers need to increase awareness and promote screening in each member state adapted to the age group. The focus in younger women will be to educate about the lifestyle factors related to a breast cancer diagnosis later in life and the importance of being breast aware and informing your physician without delay of any abnormalities. Younger women should have regular clinical breast exams performed by a health care professional. Younger women with a family history of breast and/or ovarian cancer should make arrangements with their physicians for regular and appropriate checkups⁴⁸. Between the ages of 50 and 69 intensified awareness campaigns promoting the importance of mammography screening will realise benefits. Further mammography screening should be available for women ages 45-49 and 70-74 when appropriate based on their needs and assessment in the country. Policies need to be designed to ensure that patients living with breast cancer – including in the advanced stage – have the support they need to make sure the impact on their everyday lives is as low as possible and will reap the desired outcomes. National authorities will also have to ensure they prioritize healthcare resources to deliver the best outcomes in a sustainable manner. Importantly, all breast cancer patients, including those with advanced breast cancer, should be treated by a multidisciplinary and specialized team.

There are also opportunities to improve the follow-up care for breast cancer survivors, to ensure that these women are being seen by healthcare providers on a regular basis for physical, pelvic and bone health exams, and mammograms. Equally important is follow-up education for patients so that they have an awareness of the potential symptoms of local, regional and distant recurrence.

These important policy needs were further brought to light by a multi-disciplinary Expert Working Group (EWG) on metastatic breast cancer (MBC) consisting of stakeholders from across the MBC pathway in Europe, including healthcare professionals, patient advocates and informal carers' advocates, policymakers, academics, industry representatives and former healthcare payers.⁴⁹ These experts argue that there are four major areas where policy changes are most needed to improve the outcomes for MBC patients in Europe. First, the group calls for a multi-stakeholder and collaborative approach to build a knowledge-based approach to care. Second, they underline the need to improve the collection and use of real-world data in the decision-making process. Third, the experts point out the need to improve access to care and treatment for patients and, last but by no means least, to increase patient support, participation and empowerment.

44 O'Shaughnessy, J. (2005). "Extending Survival with Chemotherapy in Metastatic Breast Cancer". *The Oncologist*, 10(suppl_3), 20-29.

45 F. Cardoso, et. al. (2018) "4th ESO-ESMO International Consensus Guidelines for Advanced Breast Cancer (ABC 4)" *Annals of Oncology* 0: 1-24

46 Cleary, J., et al. (2013). "Supportive and palliative care for metastatic breast cancer: Resource allocations in low- and middle-income countries. A Breast Health Global Initiative 2013 consensus statement". *The Breast*, 22(5), 616-627.

47 Gentile, E and Wierinck, L. (2018). On breast cancer our work is far from over. Available: <https://euobserver.com/opinion/141126>.

48 Europa Donna (2008) Guide to Breast Health. Available at: <https://www.europadonna.org/wp-content/uploads/GuidetoBreastHealth-ED.pdf>

49 A multi-stakeholder collaboration. (2017). A Policy Roadmap On Addressing Metastatic Breast Cancer. Available: <https://lillypad.eu/WP/wp-content/uploads/MBC-Policy-Roadmap-Report-digital-version-17.09.2017.pdf>.



7. EUROPEAN HEALTH SYSTEMS RESPONSE TO BREAST CANCER

HOW DIFFERENT EU COUNTRIES ARE RESPONDING TO THE BREAST CANCER CHALLENGE

From the numerous insights we have gained from examining the differences in cancer care across Europe, we can conclude that costs could be significantly reduced if we treat the disease in its earliest stages before it becomes metastatic.⁵⁰

Major differences in breast cancer prevention, screening and treatment persist in Europe. For instance, all Western European countries have attained a five-year net survival rate of at least 80%, but survival is still lower in several Central and Eastern European countries, although it has increased in recent years⁵¹. While the lowest rates are generally found in Eastern Europe, even in the Western Europe, there are worrying discrepancies. For instance, Ireland spends as much per capita as France, but the life expectancy of patients five years after diagnosis is still lower in Ireland than in France.⁵² This underscores the point that in parallel to the need to invest in cancer care, there is also a need to focus on how to best spend this money.

ANALYSIS OF SPENDING LEVELS ON TREATMENT FOR BREAST CANCER

The UK spends only 8% of its cancer budget on breast cancer. This is 3% lower than Germany and 7% lower than the spend in the Netherlands, which are amongst the highest spending countries in Europe. In terms of per capita spending, the difference between the UK, Germany and the Netherlands becomes even more pronounced⁵³. The UK spends €10.24 per capita on breast cancer, whilst Germany spends almost triple this amount on breast cancer (€28.05 per capita). The Netherlands, which has a similar incidence rate to the UK, spends €36.45 per capita on breast cancer⁵⁴.

However, it should also be mentioned that fragmentation in spending levels on treatment for breast cancer can also be found within countries, as can disparities in access to care and outcomes of cancer patients.

In terms of how equitable access to breast cancer treatments are across Europe, data shows that the uptake of trastuzumab for the treatment of breast cancer in the UK was below that of the other big five EU countries over the past decade. In addition, and importantly, in several Eastern European countries, trastuzumab is only available for early breast cancer and not for metastatic disease, with clear negative impact on the survival of HER2+ advanced breast cancer patients.

POPULATION-BASED MAMMOGRAPHY SCREENING PROGRAMS

Population-based breast cancer screening programs began in the 1980s in Sweden (1986), Finland (1987), UK (1988), and the Netherlands (1989). 26 EU Member States currently have regional or national registries, which support the cancer control programs by tracking data.⁵⁵ As of 2017, 25 of 28 Member States are either planning, piloting, or rolling out population-based breast cancer screening programs or had already established them.⁵⁶ The coverage of these screening programs varies across Member States. The highest participation rate for women ages 50-69 was in Denmark (84%) and the lowest in the Wallonia region of Belgium (6%). Large inequities in screening therefore remain within many European countries. A key challenge is how to reach out to socio-economically disadvantaged women.⁵⁷

50 Gentile, E and Wierinck, L. (2018). On breast cancer our work is far from over. Available: <https://euobserver.com/opinion/141126>.

51 OECD/EU (2018), Health at a Glance: Europe 2018: State of Health in the EU Cycle, OECD Publishing, Paris

52 Gentile, E and Wierinck, L. (2018). On breast cancer our work is far from over. Available: <https://euobserver.com/opinion/141126>.

53 ABPI. (2017). UK breast cancer care outcomes: A comparison with Europe. Available: <http://cancercomparator.abpi.org.uk/resources/ABPI%20breast%20cancer%20briefing%20July%202017.pdf>

54 Jonsson, B., Hofmarcher, T., Lindgren, P., Wilking, N. "Comparator report on patient access to cancer medicines in Europe revisited". IHE Report 2016:4, IHE: Lund

55 Eurohealth/European Institute of Women's Health. (2017). Women and Breast Cancer in the EU – a Life Course Approach. Available: <https://eurohealth.ie/women-and-breast-cancer-in-the-eu-a-life-course-approach/>

56 Ibid

57 Ibid



MULTIDISCIPLINARY SPECIALIST BREAST UNITS

There is a wide variation of breast cancer care among and within European countries, and in particular still a lack of access to multidisciplinary specialist breast units (SBU). Wide variations in healthcare systems and professional working can mean that many patients are not treated according to multidisciplinary guidelines. This is the case even in high-resource countries that have cancer plans.⁵⁸ Furthermore, there is still considerable variation in the training for breast surgical specialists as there is no standardization of training across Europe, which further results in a great disparity in surgical treatments in breast cancer⁵⁹. A recent study in Germany highlighted the value of certified multidisciplinary SBUs in showing a statistically significant improvement in guideline-adherence and overall survival for patients treated at multidisciplinary SBUs following the certification process⁶⁰.

A “European Breast Cancer Conference manifesto on breast centres/units”⁶¹ was published in 2016 by several medical and patient organisations and underlines this important need. The manifesto’s aim is to call on policy-makers and politicians to ensure that all breast cancer patients in Europe are treated in a SBU. In order to achieve this, the manifesto argues that we need to promote the evidence that breast units staffed with specialist multidisciplinary teams deliver superior care and quality of life to patients. We further need to acknowledge the evidence that treatment in multidisciplinary units leads to overall cost savings as well as a higher quality of care. Finally, the manifesto calls on policy-makers to audit the current national provision of breast cancer care and implement mandatory reimbursement and care models that mean treatment can only be carried out in SBUs, as well as introducing a breast unit quality certification scheme that is accredited by an accreditation body.

8. BREAST CANCER POLICY ACROSS EUROPE

MILESTONES IN EU CANCER POLICY

Despite healthcare governance within the European Union being predominantly a competence of the individual member states, the European Union does have a mandate and obligation in the policy domain of public health. In this respect, EU institutions play a key role in promoting policies to ensure cancer care and resources’ prioritization across Europe.

With the adoption, in 2009, of the Communication on Action Against Cancer: European Partnership⁶², the European Commission reinforced its long-term commitment to the fight against cancer by launching the European Partnership for Action Against Cancer (2009-2013).⁶³ The partnership aimed to ensure that integrated cancer plans are in place in all EU countries (resulting in an increase from 17 plans in 2009 to 25 today); reduce the incidence of cancer in the EU by 15% by 2020; and carry out 500 million screening examinations for breast, cervical and colorectal cancer between 2010-2020. In terms of breast cancer specifically, the plan also suggested the development of a voluntary European pilot accreditation scheme for breast cancer screening and follow-up, building on the European guidelines for quality assurance in breast cancer screening and diagnosis⁶⁴ (fourth edition published in 2006 and supplemented in 2013) as the most longstanding and developed guidelines in the area. Moreover, since 2014, a Commission Expert Group on Cancer Control⁶⁵ has been set up to help draw up legal instruments, policy documents, guidelines and recommendations on cancer control at the request of the Commission as well as facilitate the coordination and exchange of information between Member States.

The EU Joint Action on Cancer Control⁶⁶ (CANCON - 2014-2017), an EU-financed collaboration among European public health institutes and stakeholders to foster a quality-based screening program and better integration of care, was an important milestone in the development of EU cancer policy. Of particular relevance, it delivered a European Guide on Quality Improvement in Cancer Control⁶⁷, with evidence-based recommendations to reduce inequalities in cancer care, including recommendations of relevance for breast cancer care.

58 Krishnaswamy, J., (2017). A manifesto for consistent, superior and multidisciplinary breast cancer care. Available: <http://governmentgazette.eu/?p=7425>

59 Rubio IT et al. (2018) Variability in breast cancer surgery training across Europe: An ESSO-EUSOMA International Survey. EJSO in press

60 Kreienberg, R., et. al. (2018). “Highly significant improvement in guideline adherence, relapse-free and overall survival in breast cancer patients when treated at certified breast cancer centres: An evaluation of 8323 patients”. *Breast*, 40, 54-59.

61 Cardoso, F., et. al. (2016). “European Breast Cancer Conference manifesto on breast centres/units”, *European Journal of Cancer*, 72, 244-250.

62 Commission of the European Communities. (2009). Communication from The Commission To The European Parliament, The Council, The European Economic And Social Committee And The Committee Of The Regions on Action Against Cancer: European Partnership. Available: https://ec.europa.eu/health/archive/ph_information/dissemination/diseases/docs/com_2009_291_en.pdf

63 ECCO. (2014). European Partnership for Action Against Cancer. Available: <https://www.ecco-org.eu/Policy/Oncopolicy/EPAAC>

64 Perry, N., et. al. (2007). “European guidelines for quality assurance in breast cancer screening and diagnosis. Fourth edition--summary document”. *Annals of Oncology*, 19(4), 614-622.

65 European Commission Expert Group. (2014). Commission expert group on Cancer Control (E03203). Available: http://ec.europa.eu/transparency/regexpert/index.cfm?do=groupDetail_groupDetail&groupID=3203

66 Cancon. (2014). Cancer Control Joint Action. Available: <https://cancercontrol.eu/archived/>

67 Ibid.



The Rational Therapy for Breast Cancer (RATHER)⁶⁸ is a noteworthy initiative related to breast cancer. An EU-financed project of the European Commission's 7th Framework Program of Research and Development, it was launched in January 2011, lasting for a period of 7.5 years. The project focuses on key aspects of breast cancer research and involves the combined efforts of six universities and two biomedical companies and a wide range of organizations.

The European Commission Initiative on Breast Cancer (ECIBC)⁶⁹, is another notable initiative aimed at ensuring and harmonizing breast cancer services quality across European countries. Launched in 2012, it involves 35 countries actively collaborating together, including EU member states, EFTA members, associate and acceding countries. The European Commission's DG Santé has allocated a total of €2,400,000 to ECIBC. The ultimate goal is to establish a European quality assurance scheme for breast cancer services, addressing all care processes, including screening, diagnosis, treatment, rehabilitation, survivorship care, and palliative care. In June 2017, it published the European Guidelines for Breast Cancer Screening and Diagnosis⁷⁰. Over the course of the next two years, approximately 90 evidenced-based recommendations regarding screening and diagnosis will be developed and published. Supplemental recommendations will also be developed and updated as new evidence and priorities emerge.

In 2015 the European Parliament published a written declaration on breast cancer.⁷¹ It called for the implementation of nationwide mammography screening and multidisciplinary SBUs by the 2016 deadline, as called for in the European Parliament resolutions of 2003 and 2006 and required by the European Guidelines for Quality Assurance in Breast Cancer Screening and Diagnosis (4th edition). The declaration stated that among the hundreds of thousands of women diagnosed with breast cancer every year, those with metastatic breast cancer should have access to, and be treated in, an SBU, and their ongoing needs for care and psychosocial services should be coordinated and supported by the SBU as per the EU Guidelines. The European Commission was also called upon to ensure that the project delivered an accreditation protocol for breast cancer services by 2016.

THE KEY ROLE OF BREAST CANCER ADVOCACY GROUPS IN EU POLICY

While there is still a significant need to improve breast services and catalyse policy change to do so, much progress has been made over the last 15 years, notably thanks to advocacy groups which play an important role in achieving changes in policy and gaining agreement to implement important breast services nationally. For instance, Europe's breast cancer advocacy organisation, Europa Donna-The European Breast Cancer Coalition has been working to ensure that women in Europe have access to accurate and up-to-date information, quality mammography screening, optimal treatment and follow up for breast cancer. Advocating for population-based mammography screening programs and for specialist breast units have been among their key priorities since 2000. Since that time, they have worked directly with Members of the European Parliament on the drafting and passage of the 2003 and 2006 European Parliament resolutions on breast cancer as well as the 2010 and 2015 European Parliament written declarations on the fight against breast cancer in the EU. After the publication of the 4th edition of the "European Guidelines for quality assurance in breast cancer screening and diagnosis" in 2006 and with the support of the European Commission, Europa Donna created its "Short Guide to the EU Guidelines"; this became a key tool in educating and convincing health professionals and policy makers of the need for implementation. This guide, now translated into 17 languages, has been instrumental in getting health systems to implement both population-based screening programs and specialist breast units in numerous EU countries.

Results speak for themselves: there were 10 national screening programs in 2002 and there are 25 in 2018; there were only a handful of countries with specialist breast units in 2002 and now there are at least 14 countries that have these units. Following Europa Donna's advocacy efforts to convince policy makers of the need for an EU wide accreditation/certification scheme to ensure that breast services meet quality standards, the Commission designated the Joint Research Centre, its science and knowledge service, to carry out the European Commission Initiative on Breast Cancer (ECIBC).

Lastly, Europa Donna also carries out annual education programs enabling advocates from their 47 member countries to be trained on best practice so that they return to their countries with knowledge and skills to insist on high quality breast services. Since 2008 Europa Donna has also made primary prevention and improving services for women with MBC priorities for advocacy and is currently providing educational initiatives in these areas as well.

In the same vein, the ABC Global Alliance, launched in November 2016, was established by the European School of Oncology (ESO) to provide all involved partners (patients/advocates, health professionals, pharmaceutical and diagnostic companies, regulators, research groups, societies, organizations and individuals) with a platform where all can work together, in projects designed to improve the lives of advanced breast cancer (ABC) patients, as well as share resources.

68 RATHER. (2016). Rational Therapy for Breast Cancer. Available: <http://www.ratherproject.com/news.php>

69 ECIBC. (2017). European Commission Initiative on Breast Cancer. Available: <https://ecibc.jrc.ec.europa.eu/>

70 Dimitrova, N., et al. (2016). "European Guidelines for Breast Cancer Screening and Diagnosis – the European Breast Guidelines". JRC Technical Reports. Available: [http://publications.jrc.ec.europa.eu/repository/bitstream/JRC104007/european%20breast%20guidelines%20report%20\(online\)%20\(non-secured\).pdf](http://publications.jrc.ec.europa.eu/repository/bitstream/JRC104007/european%20breast%20guidelines%20report%20(online)%20(non-secured).pdf)

71 Childers, N., et al. (2015). Written declaration, under Rule 136 of Parliament's Rules of Procedure, on the fight against breast cancer in the European Union. Available: <http://www.europarl.europa.eu/sides/getDoc.do?pubRef=-%2f%2fEP%2f%2fNONSGML%2bWDECL%2bP8-DCL-2015-0017%2b0%2bDOC%2bPDF%2bV0%2f%2fEN>



The Alliance is the continuation of the work being developed since 2006, initially with a Task Force and then with a dedicated Consensus Conference that, today, is responsible for the development of the international guidelines on how to manage advanced breast cancer. These guidelines are currently officially the European guidelines and are being adapted and implemented in many countries around the world, including Latin America, Africa and Asia-Pacific regions. Indeed, it is imperative that all involved partners work together worldwide, developing concrete projects with substantial impact to overcome the gaps. The ABC Global Alliance is a platform where all involved partners can come together and collaborate in these common projects and may provide support for the central coordination and implementation, as well as advocating for the overall improvement of the lives of ABC patients. The first step done by the ABC Global Alliance was the ABC Global Charter⁷² that is a comprehensive needs assessment of this field and defines 10 objective and measurable goals that can be achieved within the next 10 years. The Charter allows for a focused strategy from the Alliance as well as a way to measure if advances are being made.

The two above mentioned initiatives represent only two of many advocacy initiatives which aim at ameliorating the lives of breast cancer patients and at pushing for policy change in this sense. It is of paramount importance that these advocacy groups are able to communicate with and guide policymakers, both at EU and national level, so that health systems are adapted to the specific needs associated with the disease and to provide the best possible outcomes, while reducing discrepancies, in the breast cancer care.

POLICY ON WORKING WITH CANCER IN THE EU

As we have seen, breast cancer and advanced breast cancer poses a serious threat to patients, families and European society. Patients diagnosed with breast cancer experience a traumatic event which has devastating repercussions on all the aspects of their life from their physical state to their mental health to their social life to their professional career. Indeed, a patient's or a survivor's career is strongly impacted when he or she has to fight against the associated depression, anxiety, sleep disorders, loss of appetite, lack of interest in life, pain and fatigue, all whilst trying to maintain a balanced and successful professional life. Unfortunately, there have often cases when diagnosed patients have suffered unfair treatment and dismissals because of their illness.

At EU-level there is no legislation to specifically protect ill and terminally ill employees. The EU Employment Equality Directive (EED), which protects all workers from discrimination, provides for a framework to protect workers living with a disability, however, as there is no EU-wide agreed definition of disability, it is unclear whether 'sickness' can be considered as such. The European Commission argued that the concept of disability must be understood as referring to a limitation which results from physical, mental or psychological impairments and which hinders the participation of the person concerned in professional life, and that it does not cover 'sickness', although it can include conditions caused by incurable or curable long-term illnesses (i.e. chronic illnesses). The European Court of Justice (ECJ) has also, through jurisprudence, suggested that long-term illness can be considered a disability. Therefore, it is still difficult in theory to assess whether cancer represents a form a certain disability and is under the remit of the EED and no distinctive policy has been adopted on the matter.

Regardless of the absence of a European legislative framework surrounding the rights of cancer patients and survivors to work, the difficulty of remaining in or finding work is still a significant issue. Indeed, there are numerous hurdles for all patients and survivors, from diagnosis, which usually results in long periods of sick-leave because of medical treatments and other functional restrictions, to the 'after' period, where many cancer survivors still face long-term symptoms and impairments after their treatment ends, such as fatigue, thinking and memory problems (i.e. 'chemo-brain') and peripheral neuropathy, making it more difficult to remain in or re-enter the job market.⁷³ This issue is set only to increase due to parallel rises in cancer incidence and survival⁷⁴, a scenario which results in a growing numbers of people living – and needing to work – with the disease or with the long-term side effects.

Working during or after their illness represents an important aspect of life for patients and survivors as it helps them maintain a sense of normality and contribution to their families and lives, mitigating the shock and impact of the diagnosis and treatment. At the same time, this is also a societal problem and a threat to the European economy, with the combined cost to Europe of cancer related sick leave, underemployment and unemployment estimated at €9.4bn annually, with a considerable part assumed to be due to breast cancer, as it is the most common female form of the disease in Europe⁷⁵.

At a national level, there has been some progress in this regard, with a number of countries, such as the Netherlands, Ireland and the United Kingdom, giving cancer patients the same rights as those with disabilities and laws in Italy giving workers with cancer the right to move to part-time employment and return to full-time work after their treatment⁷⁶. However, as in many European countries a relevant legislative framework is still not in place or ambiguous⁷⁷, there is still a lot of work to be done.

72 ABC Global Alliance (2018) ABC Global Charter 2018 Available at: <https://www.abcgloballiance.org/wp-content/uploads/2018/06/ABC-Global-Charter-Booklet-June-2018-Final.pdf>

73 Braspenning, I., et al. (2018). "Rehabilitation and return to work after cancer — instruments and practices". European Risk Observatory Report. Available: <https://osha.europa.eu/en/tools-and-publications/publications/rehabilitation-and-return-work-after-cancer-instruments-and>

74 Economist Intelligence Unit. (2017). Cancer in the workplace. Available: <http://cancersurvivorship.eiu.com/briefing-paper/>

75 Economist Intelligence Unit. (2017). The Road to a Better Normal: Breast cancer patients and survivors in the EU workforce. Available: https://perspectives.eiu.com/sites/default/files/EIU-Pfizer_The%20Road%20to%20a%20better%20normal_Breast%20cancer%20patients%20and%20survivors%20in%20the%20EU%20workforce_0.pdf

76 Economist Intelligence Unit. (2017). The Road to a Better Normal: Breast cancer patients and survivors in the EU workforce. Available: https://perspectives.eiu.com/sites/default/files/EIU-Pfizer_The%20Road%20to%20a%20better%20normal_Breast%20cancer%20patients%20and%20survivors%20in%20the%20EU%20workforce_0.pdf

77 McIntyre, P. (2008). "Protection of employment rights: still work in progress". Cancer World. Available: http://cancerworld.net/wp-content/uploads/2017/07/3146_pagina_56-61_patientvoice.pdf



In 2017, the European Agency for safety and health at work launched a project named “Rehabilitation and return to work after cancer— instruments and practices”.⁷⁸ The project intends to provide new insights into the problems encountered by workers affected by cancer and their employers and to make recommendations regarding successful instruments, interventions, programs and practices to support the return to work (RTW) of workers affected by cancer. It will inform policy on the emerging issue of rehabilitation and RTW after cancer and provide national administrations with examples of successful policies and interventions.

9. CONCLUSION

In the face of the situation we have described in this paper, on 4 April 2018 the ‘Transforming Breast Cancer Together’ group published a ‘[Call for Change](#)’, to increase the understanding of the daily realities of living with breast cancer in Europe and ensure policymaking reflects both the individual and the societal disease burden. The document called on EU institutions, EU Member States’ and all relevant stakeholders to:

1. Invest in both primary and secondary prevention to highlight risk factors and ensure breast cancer is screened, diagnosed and treated at an early stage, when there is the greatest opportunity to ensure the best long-term survival;
2. Ensure implementation of nationwide mammography screening programs conducted in accordance with the New European Guidelines being developed by the ECIBC across Europe. See Recommendations from European Breast Guidelines;
3. Ensure that every patient diagnosed with breast cancer has access to treatment in a specialist breast-unit (centre) by a multidisciplinary team including patients with advanced and metastatic breast cancer. Ongoing needs for care and psychosocial services for all women with breast cancer should be co-ordinated by the specialist breast unit. See Written Declaration of 2015, Manifesto on specialist breast units;
4. As part of cancer care, provide greater support to patients who relapse and develop advanced breast cancer or receive their first diagnosis in the advanced setting, in line with the ABC Global Charter developed by the ABC Global Alliance;
5. Maximise the opportunities for patients to flexibly return to work, look after their families and contribute to society before, during and after treatment. To support this, develop information, guidelines and examples of best practice for reference and use by employees with cancer, employers, carers, family members, and health professionals in all EU Member States;
6. Support health professionals in improving patient-centred communication, notably by including a training course requirement on physician-to-patient communication in university curricula throughout Europe;
7. Ensure more attention is dedicated to improving the quality of life and emotional well-being of patients and their families, with a special attention for those with advanced disease and terminal conditions.
8. Put in place a harmonized breast cancer registry process in Europe for collecting breast cancer data, both for early breast cancer and metastatic breast cancer; it is crucial that all cancer registries collect data on staging at diagnosis and date/site of first relapse, as currently this is not consistently done. Ideally this should include data on patient quality of life wherever possible;
9. Maintain a favourable environment for the development of innovative health technologies for breast cancer patients.

⁷⁸ Braspenning, I., et al. (2018). “Rehabilitation and return to work after cancer — instruments and practices”. European Risk Observatory Report. Available: <https://osha.europa.eu/en/tools-and-publications/publications/rehabilitation-and-return-work-after-cancer-instruments-and>

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