

Transforming Breast Cancer Together Renewed Call for Change

in view of the implementation of the European
Commission's Europe's Beating Cancer Plan

The COVID-19 pandemic has acted as a global wake-up call, exposing the deep-rooted vulnerabilities of healthcare systems across Europe and setting health as a top priority on the EU political agenda. Among its unprecedented consequences, COVID-19 has had devastating effects on cancer patients across Europe, with countries reporting cancer screening as the most disrupted service (49% of 86 countries), huge numbers of delayed diagnoses and cancer treatments (32% of 86) and patients' reluctance to seek medical care due to fear of contracting COVID-19.¹

Transforming Breast Cancer Together (TBCT) initiative recognised the impact and challenges of COVID-19 and published a statement to shed light on this issue in 2020². The European Parliament's Special Committee

on Beating Cancer (BECA) recently published results of the public consultation³, to which TBCT contributed, further outlining the impact of COVID-19 on the cancer pathway. The report shows a clear picture of what it means to live with cancer and breast cancer during the pandemic and reported amongst other things an increase in stress, anxiety and depression linked to the pandemic and its impact on care.

This is a crucial time to draw learnings from this pandemic and to take decisive action to address the disruptions caused to the continuity of cancer care, as well as to apply the few positive learnings we had from the crisis. Therefore, TBCT commends the European Commission for launching the ambitious and comprehensive Europe's Beating Cancer Plan (EBCP),

1 <https://www.who.int/publications/i/item/WHO-2019-nCoV-EHS-continuity-survey-2021>.

2 https://ecpc.org/wp-content/uploads/2020/04/TBCT_COVID19_Statement-3.pdf

3 <https://www.europarl.europa.eu/cmsdata/233010/Synopsis%20report%20BECA%20COVID-19%20Consultation%201228560EN.pdf>

which signals the EU's readiness to step up the fight against cancer and ensure equitable, affordable and sustainable cancer prevention, screening and early detection, treatment as well as the highest quality of life for cancer patients, survivors, their families and carers.

In our view, it is critical to ensure that those affected by breast cancer can access safe and quality procedures throughout the care pathway, from early diagnosis through treatment, including end-of-life care, and after-care. The 'right to be forgotten' is especially important when it comes to improving the quality of life for cancer survivors. At the same time, a "right to be remembered" is essential for adjustments for survivors and advanced cancer patients to be taken into account in their everyday life, with a prime example being the workplace.

TBCT believes that the publication of the Plan is the first step, while the most pivotal success factor will be dependent on the Plan's execution. To achieve the Plan's purposeful goals and to maximise its potential, it will be essential for policy and decision-makers to support the Member States in the implementation of the European Plan. This can be done by ensuring that all EU Member States have National Cancer Control Plans, by strengthening the existing National Cancer Plans that are already in place, by building a robust framework for sharing information, expertise and best practices and by implementing the EBCP in areas where no Member State can act alone.

It is important to promote meaningful and active involvement of patient organisations in the implementation process of the EBCP. The operational role of patient organisations as stakeholders should be strengthened in order to ensure the successful implementation of the Plan, centred around patient needs.

Overall, TBCT members applaud the ambitious scope of the Plan and would like to bring to the attention of the European Commission, the European Parliament and Member States, key recommendations that are pivotal for the successful implementation of EBCP.

Therefore, we urge policymakers to:

1. FOCUS ON PRIMARY AND SECONDARY PREVENTION

To achieve tangible results, it is essential to coordinate and support Member States' efforts in developing comprehensive national strategies and programmes for the primary and secondary prevention of breast cancer.

Various factors over the course of a person's lifetime can impact the risk of developing breast cancer. While it is important to consider that some are not modifiable (i.e. ageing, genetic predisposition or family history), it is encouraging that it is possible to reduce the risk of breast cancer through clear-cut actions and initiative regarding lifestyle choices.

Consequently, TBCT welcomes the European Commission's initiatives and prevention programmes in this area supported with adequate funding, including the Healthy Young initiative and Fit EU, promoting physical activity and healthy diets and aiming to control alcohol consumption. Additionally, TBCT stresses the need for public funding to support research on the impact of changeable lifestyle aspects on cancer prevention and recurrence, with the aim of collecting more evidence-based information on this issue.

TBCT urges the Commission to effectively involve patient organisations as active stakeholders in the process of creating and implementing European-wide prevention campaigns, who will be able to contribute at different levels and ensure that the objectives are in line with patients' needs and expectations.

Many breast cancer deaths are preventable and therefore timely access to screening and treatment is crucial to reduce the rate of the breast cancer epidemic. Treating breast cancer while it is still at an early stage provides patients with the best chance of cure, thereby reducing the burden of disease to patients, families, and society. Special considerations should be given to the importance of metastatic breast cancer patients and breast cancer survivors maintaining a healthy lifestyle

to prevent recurrence. It should also be noted that most breast cancer cases occur in post-menopausal women. In light of this, TBCT recommends that the aforementioned initiatives should aim to include people of all ages and conditions irrespective of where they are in their cancer journey.

Finally, while the Plan focuses on the modifiable risk factors, it is equally important to support the process of identifying new risk factors for developing cancers. TBCT emphasises the need to implement a two-pronged approach that aims to address both funding and budget considerations for research and preventative actions including access to genetic counselling and testing and effective management of BRCA carriers.

2. INVEST IN EARLY DETECTION

Undoubtedly, the early stage of detection and diagnosis of breast cancer is pivotal to increasing the chances of the successful and effective treatment and ultimately, survival of breast cancer patients.

Therefore, TBCT welcomes the European Commission's ambition to attaining 90% coverage on breast cancer screening and early detection and believes that this is essential to achieve better clinical prognosis, lower mortality rates and reduce treatment costs. We recognise the enormous benefits that this could bring to women's health, especially, if coupled with a similar screening target for the second most common type of cancer among women, namely, cervical cancer.

The European Commission should aim to establish a European platform for screening programmes that are audited, follow predetermined standards and are in line with evidence-based guidelines. TBCT recommends that the guidelines should include quality indicators to cover the structure, process and outcome of the screening programmes to measure their effectiveness. To overcome barriers to equal access to screening and treatment, we urge the Commission to invest in and work with Member States and communities where screening numbers are low.

While establishing a new initiative is commendable and should be done when it comes to closing gaps in screening programmes across Europe, a multitude of initiatives already exist to support early detection. It is important to focus on these existing initiatives and avoid directing similar resources to parallel processes. To that end, TBCT calls on all EU institutions to join efforts to encourage Member States' national, population-based screening programmes that are set up according to the European Commission Initiative on Breast Cancer (ECIBC) screening guidelines.⁴

In addition to the above, TBCT urges the European Commission to invest in early detection and implement specific tools to improve early diagnosis. Notably, for women in the EU, diagnosed at an early or localised stage, the cumulative probability of surviving the disease for at least five years after diagnosis is on average 96%. However, survival for women diagnosed at an advanced stage is still low at 38%.⁵ In light of this information, the Commission should aim to empower more diagnostic investigation to be carried out at the primary healthcare level, to incentivise providers of high-quality preventative care, to establish comprehensive genomic profiling that could be accessible in clinical practice and to facilitate a self-learning healthcare system which will connect to patient profiles and provide information about appropriate care plans.

3. ENSURE EFFECTIVE AND QUALITY BREAST CANCER CARE AND TREATMENT

The quality of cancer care is of the utmost importance and to achieve this, breast cancer patients should be treated in accredited centres by a multidisciplinary and specialised team. Thus, TBCT warmly welcomes the European Commission's ambition to ensure that all EU Member States have Comprehensive Cancer Centres (CCCs) by 2025. It is important that the CCCs are equipped and ready to address the specific needs of breast cancer patients including advanced and metastatic breast cancer patients.

⁴ <https://ec.europa.eu/jrc/en/publication/european-guidelines-breast-cancer-screening-and-diagnosis-european-breast-guidelines>

⁵ Health at a Glance: Europe 2020: State of Health in the EU Cycle, <https://www.oecd-ilibrary.org/sites/c63a671a-en/index.html?itemId=/content/component/c63a671a-en>

In light of this, TBCT acknowledges the inter-speciality training programme set out in the Plan to support the training and education of health personnel. Besides technical training, good communication must also be reinforced to ensure that patients receive adequate information in a timely manner. To ensure the programme's success we believe there is a need for developing programs for specific certifications. Given that surgeons trained in cancer surgery are a key factor affecting outcomes and quality of life of breast cancer patients, we highlight the need for certified breast-cancer specialised surgeons to provide the best quality of care. TBCT would like to bring to the attention of the policy-makers the European Breast Surgical Oncology Platform 'BRESO', formed by European Cancer societies that has developed and implemented a dedicated certification programme in breast cancer surgery.⁶ Furthermore, systemic therapy should be managed by specialised medical oncologists, which is still not the case in all Member States.

Access to innovative oncology medicines varies significantly among and within EU countries undermining patients access to new, promising therapies. For instance, access to innovative oncology medicines can vary significantly with 7% to 98% positive reimbursement decisions following the European Marketing Authorisation in Latvia and Germany, respectively⁷. Additionally, the time taken by national approval systems to take such decisions ranges from a few months up to 2-3 years in some Member States. Hence, TBCT encourages the European Commission to tackle access restrictions and delays by improving the efficiency of the European Medicines Agency's processes by favouring the adaptation of fast approval processes as was the case for the approval of COVID-19 vaccines. Equally the timely implementation of Health Technology Assessment (HTA) processes, avoiding duplications of clinical assessments at the national level as well as proper consideration of the value of combination treatments and of surrogate endpoints can contribute to improving patient access.

It is also important to display different solutions for people living in remote rural areas or distant from accredited national centres. Investment in digital tools and e-health and other emerging flexible treatment options such as providing innovative treatment at home can help.

4. REDUCE THE DISPARITIES ACROSS EUROPE AND PROMOTE DIGITALISATION

TBCT welcomes the recognition of the importance of addressing the inequalities across Europe and the Plan's introduction of the Cancer Inequalities Register. However, to effectively monitor the impact of inequalities, the Plan should foster the implementation of the various National Cancer Control Plans by measuring progress, via European targets in the areas of prevention, screening, treatment, survivorship and social rights. A public facing measurement system with key performance indicators would hold everybody accountable for implementation.

As previously addressed in TBCT's response to the European Commission's European Health Data Space (EHDS) consultation⁸, we believe that there should be a harmonised breast cancer registry process in Europe for collecting breast cancer data, including both early and metastatic breast cancer.

Despite the devastating effects the pandemic has had, the COVID-19 crisis is not without positive learnings. Remarkable scientific advances have facilitated enormous progress in healthcare systems, including innovation of home-based care, flexibility in clinical trials implementation, development of digital tools, patient-friendly apps and care pathways organised around patients' needs.

Therefore, TBCT urges the European Commission to leverage these developments and embrace the advantages of the digital era, and we recommend that

6 Kovacs T et al. Theoretical and practical knowledge curriculum for European breast surgeons. *Eur J Surg Oncol* 2020 Apr;46(4 Pt B):717-736 doi: 10.1016/j.ejso.2020.01.027, <https://breasturgeoncertification.com>

7 Access challenges within Europe in terms of Patient Access and Market Access. e.g. PL reports reimbursement for a therapy 891 days after the European Market Authorisation and only 24% of patients receiving treatment 12 months after the decision. <https://www.efpia.eu/media/578013/every-day-counts.pdf>

8 https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/12663-Digital-health-data-and-services-the-European-health-data-space/F1574226_en

the Cancer Plan should aim to work together with the new European Health Data Space initiative to foster harmonisation of digital standards, governance and data infrastructure at European level and invest in upscaling coordination and cooperation mechanisms that will enable registries to collect data consistently and in a homogenous way.

It is in patients' interests to effectively involve the use of Artificial Intelligence and machine learning. We urge the European Commission to deploy these new technologies to develop better targeted screening mechanisms, to improve personalised medicine, to accelerate and refine the quality of diagnosis by standardising tasks, to monitor the survivors' conditions and follow-up treatments and to improve care for metastatic / advanced patients.

5. STRIVE TO IMPROVE THE QUALITY OF LIFE OF BREAST CANCER PATIENTS

Adding to the numerous hurdles all patients and survivors have to face throughout their cancer journey, the COVID-19 pandemic has disproportionately affected the quality of life of cancer patients. There are various obstacles for all patients and survivors, starting from diagnosis, which usually results in long periods of sick leave due to medical treatment 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 and peripheral neuropathy, making it more difficult to remain in or re-enter the job market.⁹ These symptoms are even more severe for advanced / metastatic patients, who have to endure continuous treatment.

TBCT wants to highlight the fact that having the ability to work – if they wish to – is very important for breast cancer patients and survivors as it can restore a sense of normality and wellbeing as well as contribute to financial stability and security. However, those affected by cancer find returning to work very difficult as they deal with the side effects of surgery, chemotherapy, radiotherapy and other treatments. In light of this,

TBCT urges the European Commission to place more emphasis on the issue of returning to or maintaining work and to develop and implement programmes that support breast cancer patients and survivors to do so in a flexible manner. This should include flexibility of the working location to include both physical and virtual settings, to ensure the private and societal needs of cancer patients and survivors are met before, during and after treatment.

Moreover, TBCT calls the European Commission to develop and implement information, guidelines and toolkits about returning to work, designed specifically for employees with cancer, employers, carers, family members, and health professionals in all EU Member States. In addition to this, it is necessary to strengthen and reinforce the principles and guidelines for equal opportunities and workplace inclusion of breast cancer patients and survivors, especially during this transition point.

TBCT would like to give special attention to the devastating effect of the COVID-19 pandemic on people's mental health. The mental health problems that arise as a result of a cancer diagnosis are too often ignored or overlooked. Therefore, it is crucial to dedicate more attention ever-increasing need for multidisciplinary support that should be widely available to all patients, survivors, their families and their caregivers.

TBCT was established in November 2017 with the ultimate goal to improve services for patients in an area of still high unmet need and reduce the societal impact of breast cancer by elevating it as a health policy priority in order to improve its prevention, diagnosis and care across Europe.

The initiative is chaired by TBCT Chairs MEPs Frances Fitzgerald (EPP) and MEP Patrizia Toia (S&D), ABC Global Alliance, Eli Lilly and Company, Europa Donna – The European Breast Cancer Coalition, European Cancer Patient Coalition (ECPC), European School of Oncology (ESO), European Society of Breast Cancer Specialists (EUSOMA), European Society of Surgical Oncology (ESSO), Helsinn Healthcare, Novartis, Roche, Sanofi and Working With Cancer.

⁹ <https://www.europarl.europa.eu/cmsdata/233010/Synopsis%20report%20BECA%20COVID-19%20Consultation%201228560EN.pdf>

CALL FOR IMPLEMENTATION

Our position on the European Commission’s Europe’s Beating Cancer Plan can be further understood and made concrete as a Call for Implementation. TBCT wants 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. COVID-19 and its repercussions as an additional source of worry cannot be ignored and should be considered accordingly. As such we call upon the Commission to:

1. Invest in both primary and secondary prevention, including genetic counselling, testing and management of BRCA carriers.
2. Provide adequate support to Member States, so as to achieve the EBCP’s target to offer screening to 90% of the EU population who qualify for breast cancer screenings by 2025.
3. Ensure effective and quality breast cancer care and treatment including the use of innovative health technologies for breast cancer patients.
4. Ensure that all women diagnosed with breast cancer have access to treatment in a specialist breast-unit (Centre) by a multidisciplinary team, including women with advanced and metastatic breast cancer.
5. Apply the lessons learned from the COVID-19 crisis and improve the timely approval of innovative therapies, reducing the immense inequalities in patient access between EU Member States.
6. Leverage the European Commission’s European Health Data Space plans to put in place a harmonised breast cancer registry process in the EU for collecting early breast cancer and metastatic breast cancer data.
7. Maximise the opportunities for patients to flexibly maintain or return to work, look after their families and contribute to society before, during and after treatment.
8. Ensure more attention is dedicated to improving the quality of life of patients and their families, with a special attention for those with advanced / metastatic disease and terminal conditions.
9. Improve the management of late and long-term and side effects, unmet psychosocial needs, issues related to emotional distress that negatively affect the patient’s quality of life.

ABOUT THE TRANSFORMING BREAST CANCER TOGETHER INITIATIVE

‘Transforming Breast Cancer Together’ initiative (TBCT), was established in November 2017 with the ultimate goal to improve services for patients in an area of still high unmet need and reduce the societal impact of breast cancer by elevating it as a health policy priority in order to improve its prevention, diagnosis and care across Europe.

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