Transforming Breast Cancer Together

Bridging the Gap in Breast Cancer Care

ABC GlobAlliance

European Cancer Patient Coalition

Lilly

ESO European School of Oncology
learning to care

esso
The European Society of Surgical Oncology

EUROPA DONNA
The European Breast Cancer Coalition

EUSOMA
European Society of Breast Cancer Specialists

HELSINN
Building quality cancer care together

NOVARTIS

Roche

WORKING WITH CANCER

Bridging the Gap in Breast Cancer Care

Agenda

Welcome and introduction: MEP **Frances Fitzgerald** and MEP **Patrizia Toia**

Keynote address: **Stella Kyriakides**, Commissioner for Health and Food Safety

Panel 1 - Addressing an unmet need in breast cancer care

Marzia Zambon, External Affairs Director, Europa Donna
Barbara Wilson, Director and Founder, Working With Cancer
Grazia Scocca, Legal Expert, the European Cancer Patient Coalition (ECPC)
Dr Fatima Cardoso, Director Breast Unit, Champalimaud Clinical Centre and Chair ABC Global Alliance

Panel 2 - Tackling gaps in breast cancer care

MEP Alessandra Moretti, Member of the European Parliament (S&D)
Ciarán Nicholl, Head of the Health in Society Unit, JRC, European Commission
Dr Isabel T. Rubio, President, EUSOMA and President-elect ESSO

Addressing an unmet need in breast cancer care

Panel 1 speakers

Marzia Zambon

EuropaDonna

Barbara Wilson

Working With Cancer

Grazia Scocca

European Cancer Patient Coalition

Fatima Cardoso

ABC Global Alliance

#TBCTbridgethegap

Europe’s Beating cancer Plan: Bridging the gap in Breast Cancer Care

EUROPA DONNA
The European Breast Cancer Coalition

The State of Breast Services in the European Countries

Marzia Zambon

Director of External Affairs

15 October 2020

EUROPA DONNA: 47 Member Countries

EUROPA
DONNA
The European
Breast Cancer Coalition

15 OCTOBER
BREAST
HEALTH DAY
2020
www.breasthealthday.org

Engaging in physical activity, maintaining a normal body weight and eating a healthy diet can help your breast health

Ensure that all European Women have Access to Accurate Information and Quality Screening, Diagnosis and Treatment

2020 Survey: Breast Services in Europe

Fifty-two questions, divided into five sections:

- Your country and breast cancer care
- Mammography screening and diagnosis
- Specialist Breast Units
- Metastatic Breast Cancer
- Miscellaneous, including Covid-19/cancer care

Respondents: 34 Countries **24 from the European Union**

Albania, Armenia, Belgium, Bulgaria, Croatia,
Cyprus, Czech Republic, Denmark, Estonia, Finland, France,
Germany, Greece, Ireland, Israel, Italy, Latvia, Luxembourg,
Malta, Monaco, the Netherlands, North Macedonia, Norway,
Poland, Portugal, Romania, Serbia, Slovakia, Slovenia,
Spain, Sweden, Switzerland, Turkey, and Ukraine

Allocation of Costs in Cancer Care

- National Health-care:
  - 79% National Public Level
  - 21 % Regional Level with National Control

- Breast cancer care:
  - 53% Public Health Facilities
  - 47% mix of Private and Public facilities

- 84% Costs paid by Public Health System

- 52% costs for genetic or genomic testing and certain diagnostic tests to be covered privately

- 76% Cost of supplementary aids (wigs, prostheses, lymphatic drains are (partially) reimbursed

Your Country and Breast Cancer Care

- 79% countries have national programmes/campaigns for primary prevention
  - 87,5% EU Countries
- ***59% NO committee/advisory board/group in national parliament/government, dealing with breast cancer***
- 54% countries have legislation protecting or implementing BC survivors' right to return to work
- 42% countries have legislation protecting or implementing survivors' right to access insurance
- 12% countries have passed "right to be forgotten" legislation for cancer survivors: ► **Belgium, France, Luxembourg, Israel**

Mammography Screening and Diagnosis

- 74% Organised Population-based BC Screening Programme
  - 83,3% EU Countries

- 68% Women 50-69 invited to mammography screening every two years
  - 75% EU Countries

- 62% Screening through state-of-the-art technology

- 94% of women diagnosed with BC begin treatment within a reasonable time from diagnosis

Specialist Breast Units (SBUs)

- 55% have SBU with MDTs. Of these:
  - 53% large enough to enable a minimum of 150 newly diagnosed cases of BC and treat at least 50 cases of MBC per year
  - 66% of SBUs have MDTs, some do not have a data manager or specially trained breast care nurses
  - 71% SBUs offer state-of-the-art equipment and technology and high levels of treatment
- ***34% of countries have a certification/accreditation system for SBUs and 41% have an authority in charge of monitoring the quality of SBUs***

Metastatic Breast Cancer

- 35,29% of women who have been diagnosed with MBC *DO NOT* have access to services within a SBU

- 50% say there is a lack of programmes and services providing counselling, employment and return-to work advice, addressing financial concerns, insurance coverage and family issues

- 65,63 % say there are very few registries for MBC cases

Conclusions

- National Cancer Plans 🙂
- Screening Programs 🙂
- Timely Treatment 🙂
- Specialist Breast Units 😐
- Genetic Counselling 🙁
- Accreditation 🙁
- MBC Care 🙁

EUROPA DONNA
The European Breast Cancer Coalition

Thank you!

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www.europadonna.org
info@europadonna.org

WORKING WITH CANCER

Cancer & Work: The Unmet Needs of EU Breast Cancer Patients

Barbara Wilson

15th October 2020

school for social entrepreneurs

WORKING WITH CANCER

Europe, Cancer, Work

- Breast cancer incidence 2018 approx. 404,920. or 1 in 8
- 56% are working age
- Most cancer survivors of working age want to work but fewer than two-thirds of employees have returned to work/are working 1 year post diagnosis.
- **2013 showed loss of working days due to cancer cost Eur 9.43bn**

Typical work challenges for breast cancer survivors

1. Most breast cancer survivors don’t understand their cancer, or the side effects of treatment on their work, or that recovery is not linear
2. Most employers don’t understand this either so don’t provide adequate support
3. And neither are equipped to talk about cancer
4. Most health care professionals provide inadequate information about work and cancer
5. In the EU:
   - Huge disparity and inequalities in employment practices
   - Employers ‘do not consider job preservation approaches that acknowledge patient’s residual work capacity’.*

* ECPC CHALLENGING THE EUROPE OF DISPARITIES IN CANCER

Challenges for those with advanced breast cancer.

- Life changing, side effects: physical, cognitive, psychological. Persistent, invisible, fluctuating
- Uncertainty about periods of wellness and changing treatment plans make a standard working week almost impossible
- Employers' and colleagues ignorance about life expectancy of those with advanced/metastatic cancer
- Inflexible working policies and practices

But that doesn't mean they can't work

What the EBCP should include

- Create a **dashboard** which measures and monitors return to work in each country.
- Make it **illegal to discriminate** vs those with cancer (or any chronic illness) and establish **‘the right to be remembered**’ so employers provide adjustments and support when/if employees disclose their cancer.
- Make **flexible working** a 'Day 1' right for any employee able to work from home – COVID-19 has shown this is possible for many.

For more information about WWC

www.workingwithcancer.co.uk

admin@workingwithcancer.co.uk

07910 835585

The Right to be forgotten: putting an end to discrimination

Europe’s Beating Cancer Plan : Bringing the gap in Breast Cancer Care

Grazia Scocca, Legal Specialist

European Cancer
Patient Coalition

CANCER SURVIVORSHIP

Cancer survivors need **"the Right to be Forgotten"**

France passed legislation in **January 2016**

Belgium passed legislation in **March 2018**

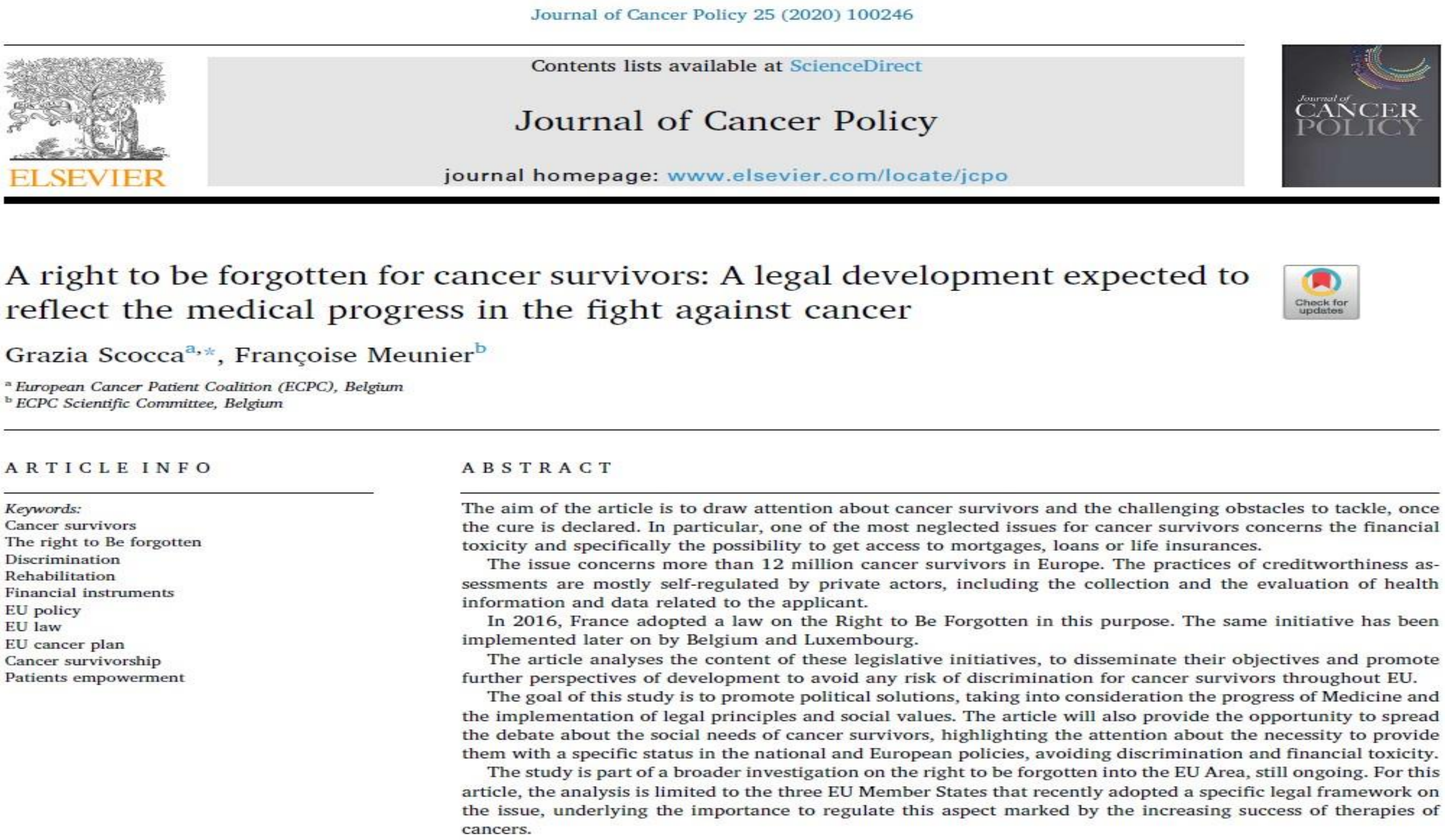
Luxembourg adopted a Convention between the Ministry of Health and the Association of Insurance and Reinsurance Companies (ACA) in **October 2019**

What about all other EU Countries?

Why not for ALL EU citizens? A new European Right

THE RIGHT TO BE FORGOTTEN LEGAL FRAMEWORK IN **FRANCE**, **BELGIUM** AND **LUXEMBOURG**

KEY-ASPECTS OF THE PROVISION:	FRANCE	BELGIUM	LUXEMBOURG
Shorter terms for cancer with better prognosis	✓	✓	✓
Shorter terms for childhood cancer survivors (>18 or >21)	✓ ***>21***		✓ **>18**
Obligation to declare the disease	There is no obligation to declare, except for the cases of cancer diseases listed in the referred table with shorter terms to apply the right to be forgotten	✓	There is no obligation to declare, except for the cases of cancer diseases listed in the referred table with shorter terms to apply the right to be forgotten
Restrictions to the amount of money to borrow	✓ Max. amount € 320,000 euros For consumer loans, under 17,000 € no request to fill out a health questionnaire	No limitation	✓ Max. amount 1,000,000 €
Financial instruments accessible	The Rights to be forgotten applies to consumers, real estate and professional loan insurance.	The Right to be forgotten concerns mortgage and professional loans.	The Right to be forgotten involves outstanding insurance for a loan or estate loans for the acquisition of the main residence or professional facilities



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A right to be forgotten for cancer survivors: A legal development expected to reflect the medical progress in the fight against cancer

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Discrimination
Rehabilitation
Financial instruments
EU policy
EU law
EU cancer plan
Cancer survivorship
Patients empowerment

ABSTRACT

The aim of the article is to draw attention about cancer survivors and the challenging obstacles to tackle, once the cure is declared. In particular, one of the most neglected issues for cancer survivors concerns the financial toxicity and specifically the possibility to get access to mortgages, loans or life insurances.

The issue concerns more than 12 million cancer survivors in Europe. The practices of creditworthiness assessments are mostly self-regulated by private actors, including the collection and the evaluation of health information and data related to the applicant.

In 2016, France adopted a law on the Right to Be Forgotten in this purpose. The same initiative has been implemented later on by Belgium and Luxembourg.

The article analyses the content of these legislative initiatives, to disseminate their objectives and promote further perspectives of development to avoid any risk of discrimination for cancer survivors throughout EU.

The goal of this study is to promote political solutions, taking into consideration the progress of Medicine and the implementation of legal principles and social values. The article will also provide the opportunity to spread the debate about the social needs of cancer survivors, highlighting the attention about the necessity to provide them with a specific status in the national and European policies, avoiding discrimination and financial toxicity.

The study is part of a broader investigation on the right to be forgotten into the EU Area, still ongoing. For this article, the analysis is limited to the three EU Member States that recently adopted a specific legal framework on the issue, underlying the importance to regulate this aspect marked by the increasing success of therapies of cancers.

Thank you!

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EUROPE'S BEATING CANCER PLAN: BRIDGING THE GAP IN BREAST CANCER CARE

15 OCTOBER 2020, 12:00-13:30 CEST

Breast cancer is the most diagnosed cancer in women in Europe. Despite recent advancements, disparities in treatment and care between and within EU countries remain. Breast cancer still represents a major threat to European citizens and society as it has a profound social and emotional impact, and is also a huge personal and professional burden for patients, survivors and their families. However, numerous issues and challenges of living with early and advanced breast cancer are not well recognised by the general public and policymakers.

To mark Breast Cancer Awareness Month, Transforming Breast Cancer Together members would like to shed light on the challenges and often invisible realities of living with early and advanced breast cancer. During the event, we aim to present recent studies and ongoing initiatives focused on addressing the unmet needs in early and advanced breast cancer care, raise awareness around the burden of the disease and facilitate the discussion with EU stakeholders and policymakers about the daily challenges patients face. Also, we will discuss how Europe's Beating Cancer Plan can bring yet better outcomes to European patients, their families and society.

We look forward to seeing you.

KEYNOTE:

Stella Kyriakides,
Commissioner for Health and Food Safety

CONFIRMED SPEAKERS:

- **Frances Fitzgerald**
  Member of the European Parliament (EPP)
- **Patrizia Toia**
  Member of the European Parliament (S&D)
- **Alessandra Moretti**
  Member of the European Parliament (S&D)
- **Dr Fatima Cardoso**
  Director Breast Unit, Champalimaud Clinical Centre and Chair ABC Global Alliance
- **Marzia Zambon**
  External Affairs officer, Europa Donna – The European Breast Cancer Coalition
- **Barbara Wilson**
  Founder and Director of Working With Cancer
- **Grazia Scocca**
  Legal Expert, European Cancer Patient Coalition (ECPC)
- **The European Commission** (TBC)

The event will be **moderated by Petra Wilson**, FTI Consulting

Chatham House rules will not apply.

ABC Global Alliance Awareness Campaign
Invisible Woman 2.0
A multi-stakeholder approach in optimising ABC patients' needs

F. Cardoso, MD
Director, Breast Unit, Champalimaud Clinical Center, Lisbon, Portugal
Chair, ABC Global Alliance and ABC Guidelines
ESO Scientific Committee

European School of Oncology
learning to care

College of the European School of Oncology

ABC GlobAlliance

The ABC Global Alliance

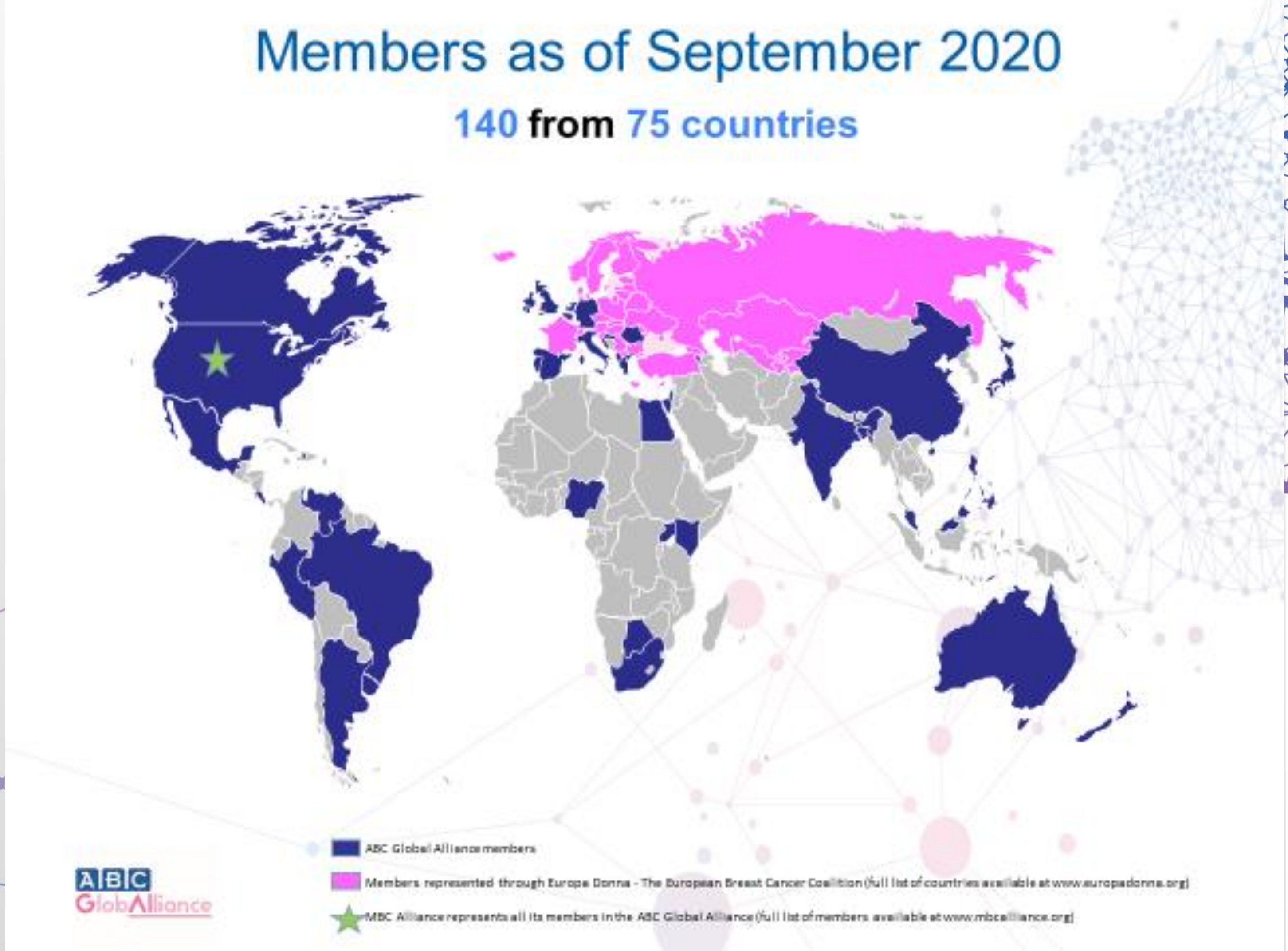
Continuing the work of the ABC Consensus Conference and Guidelines

GET TOGETHER!
COLLABORATE!
SHARE RESOURCES AND KNOWLEDGE!

Website www.abcglobalalliance.org

Email rventura@abcglobalalliance.org

Social media @ABCGlobalAll

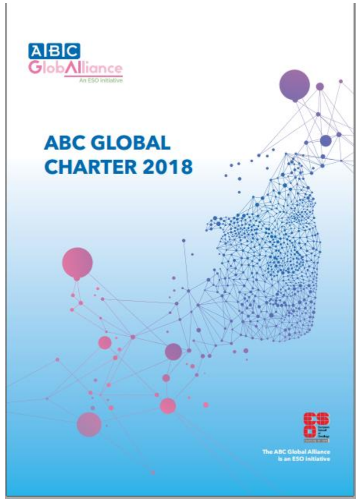


Members as of September 2020

140 from 75 countries

- 🟦 ABC Global Alliance members
- 🟪 Members represented through Europa Donna - The European Breast Cancer Coalition (full list of countries available at www.europadonna.org)
- ★ MBC Alliance represents all its members in the ABC Global Alliance (full list of members available at www.mbcalliance.org)

ABC Global Charter
10 goals for the next 10 years



ABC GlobAlliance
An ESO initiative

ABC GLOBAL CHARTER 2018

The ABC Global Alliance is an ESO initiative

COMPREHENSIVE NEEDS ASSESSMENT
DEFINES MOST URGENT AND ACTIONABLE GOALS
Done with (almost) all different stakeholders involved in ABC

1. HELP PATIENTS WITH ABC LIVE LONGER BY DOUBLING ABC MEDIAN OVERALL SURVIVAL BY 2025
2. ENHANCE OUR UNDERSTANDING ABOUT ABC BY INCREASING THE COLLECTION OF HIGH QUALITY DATA
3. IMPROVE THE QUALITY OF LIFE (QOL) OF PATIENTS WITH ABC
4. ENSURE THAT ALL PATIENTS WITH ABC RECEIVE THE BEST POSSIBLE TREATMENTAND CARE BY INCREASING AVAILABILITY OF ACCESS TO CARE FROM A MULTIDISCIPLINARY TEAM
5. IMPROVE COMMUNICATION BETWEEN HEALTHCARE PROFESSIONALS (HCP) AND PATIENTS WITH ABC THROUGH THE PROVISION OF COMMUNICATION SKILLS TRAINING FOR HCPS
6. MEET THE INFORMATIONAL NEEDS OF PATIENTS WITH ABC BY USING EASY TO UNDERSTAND, ACCURATE AND UP-TO-DATE INFORMATION MATERIALS AND RESOURCES
7. ENSURE THAT PATIENTS WITH ABC ARE MADE AWARE OF AND ARE REFERRED TO NON-CLINICAL SUPPORT SERVICES
8. COUNTERACT THE STIGMA AND ISOLATION ASSOCIATED WITH LIVING WITH ABC BY INCREASING PUBLIC UNDERSTANDING OF THE CONDITION
9. ENSURE THAT PATIENTS WITH ABC HAVE ACCESS TO TREATMENT REGARDLESS OF THEIR ABILITY TO PAY
10. HELP PATIENTS WITH ABC CONTINUE TO WORK BY IMPLEMENTING LEGISLATION THAT PROTECTS THEIR RIGHTS TO WORK AND ENSURE FLEXIBLE AND ACCOMMODATING WORKPLACE ENVIRONMENTS

ABC GlobAlliance

Website www.abcglobalalliance.org
Email rventura@abcglobalalliance.org
Social media @ABCGlobalAll

Public perceptions may perpetuate the **stigma and isolation** for mBC patients

On average, **28%** of the general population indicated that
patients with mBC should **keep it a secret**
and **not discuss it** with anyone other than their physician

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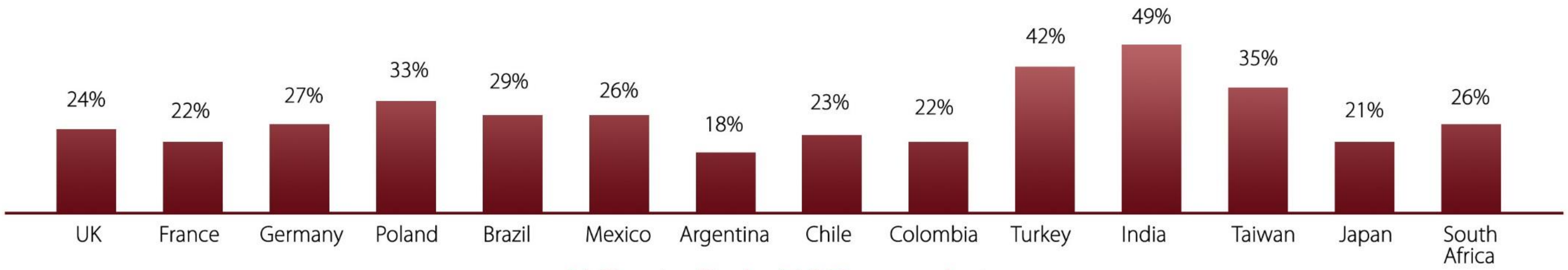
Percentage of respondents that felt people with advanced or metastatic breast cancer should not talk about it with anyone other than their physician

(% Agree somewhat/strongly - top 2 box)



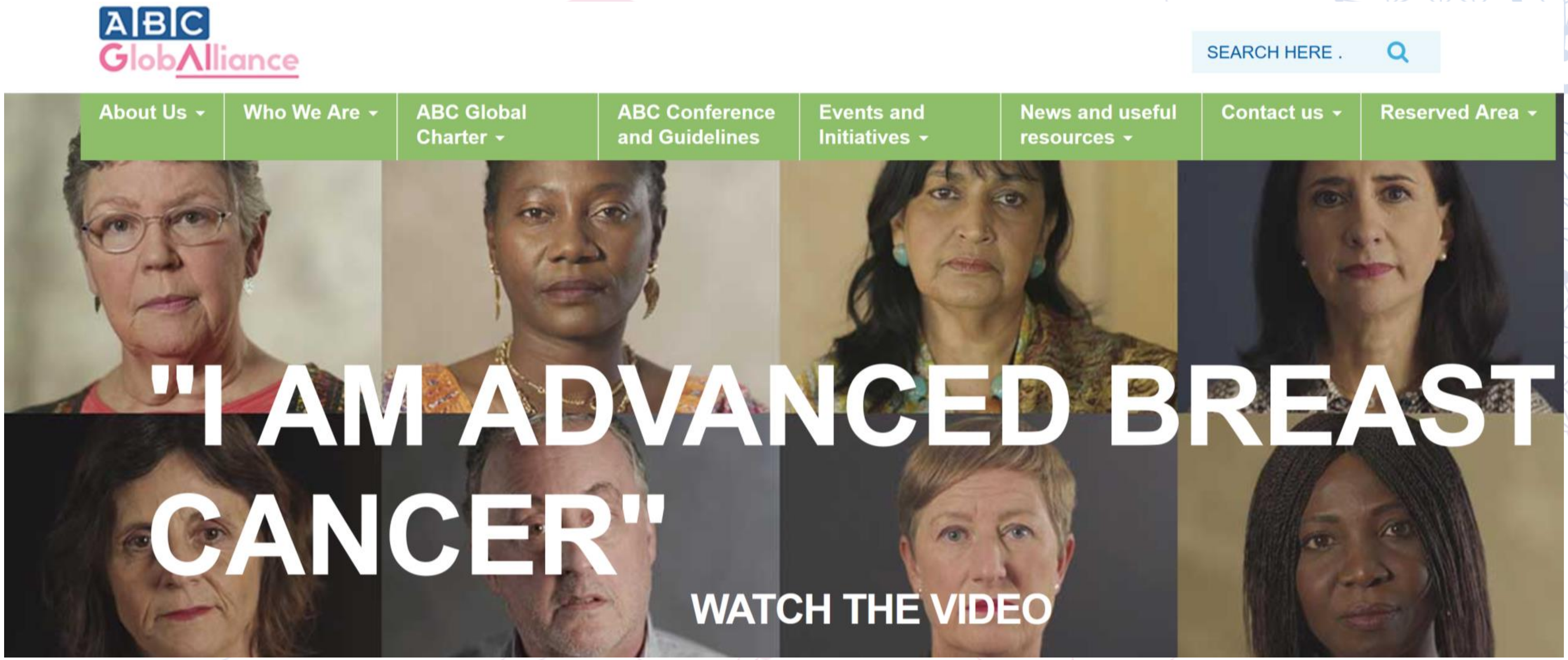
14 Country Study: 14,315 respondents

GLOBAL STATUS OF mBC DECADE REPORT

8 (Goal n° 8)

Awareness Campaign

COUNTERACT THE STIGMA AND ISOLATION ASSOCIATED WITH LIVING WITH ABC BY INCREASING PUBLIC UNDERSTANDING OF THE CONDITION



"I AM ADVANCED BREAST CANCER"

WATCH THE VIDEO

Video is published on website and on Youtube (https://youtu.be/4zbvXW6BQXc)


The Invisible Woman 2.0

A pan-European research

Campaign Assets


nvisible Woman

2013

Launch of Here&Now Campaign

The Invisible Woman report


HE
NVISIBLE
WOMAN 2.0
2020
REPORT

2020

MyTimeOurTime Campaign

The Invisible Woman 2.0 report

Same questionnaire

Ketchum x

A total of 98 respondents reached in 8 EU countries, majority of them are carers

8 Countries **98** Respondents **36%** Patients **64%** Carers

30 minute computer assisted web interview (CAWI)

BELGIUM	
TOTAL	4
NETHERLANDS	
TOTAL	4
FRANCE	
TOTAL	25
SPAIN	
TOTAL SAMPLE	26

	SWEDEN
5	TOTAL
	POLAND
5	TOTAL
	ITALY
26	TOTAL
	ISRAEL
3	TOTAL SAMPLE

Ketchum x

Key headlines: personal impact

INITIAL BC DIAGNOSIS

At initial diagnosis of BC, patients spontaneously expressed fear, shock, grief and depression – similar emotions to those seen in 2013

aBC DIAGNOSIS

The aBC diagnosis takes a huge emotional toll, with 58% of patients (vs 37% in 2013) stating that they have lost confidence since diagnosis

THESE DAYS

In physical terms, nearly 60% (vs 50% in 2013) of patients say that they now have pain and discomfort that interferes with daily life; 43% (vs 30% in 2013) require help from family members for personal care

my time our time

NOVARTIS

Key headlines: societal & economic impact & information needs

SOCIETAL IMPACT

Roles and responsibilities

Keeping the family together

Pre aBC

46% → 25%

Post aBC

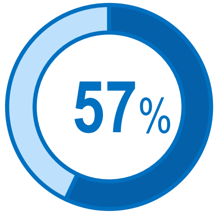
Isolation

From early BC community

How society sees women with aBC

Pity

ECONOMIC IMPACT



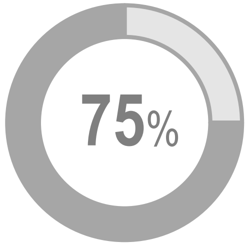
Patients in paid **employment**

75% Had to make changes to employment post diagnosis

Suffered **income decline**

70% **Suffered stress** due to changes in financial situations

SUPPORT & INFORMATION NEEDS



Patients who would feel better informed if they had **more time to discuss the diagnosis**

Biggest area followed by treatment access that **need improvement**

QoL

% of respondents

Ketchum x

QoL= Quality of life

The Invisible Woman 2.0 report - Five years on

A report that highlights what's changed and what remains the same for women with ABC from a societal, psychological and financial perspective - since the first report was launched in 2013.

Check the full report at:
https://www.wearehereandnow.com/invisible-woman.html

THE INVISIBLE WOMAN 2.0 2020 REPORT

Introduction

"The survey showed that many women with aBC were suffering from psychological, social and financial hardships. Support and guidance were offered, but they were insufficient."

There currently remains no cure for advanced breast cancer (aBC), and women who live with the disease are faced with a range of personal, social and economic challenges, impacting their ability to work and carry out daily tasks.

The first Invisible Woman Report[1] based on the Here & Now Patients and Carer Survey, published in 2013, aimed to raise awareness of aBC and provide pioneering insights into the impact of the disease on patients, families, society and economies across Europe. The survey showed that many women with aBC were suffering from psychological, social and financial hardships. Support and guidance were offered, but they were insufficient. Patients and carers were often unable to get adequate information about aBC, and they often felt depressed, worried, and feared for the future. Many patients were forced to take on less responsibility and had to give up paid employment or reduce the hours that they worked. They were also less able to look after their families. The report helped shine some light on the value of the contribution that women aged 50+ make to society, whilst also delivering recommendations on how these findings could be used to improve care and support for those affected by aBC.

"This report aims to further explore the aBC patient landscape in Europe and provide clear comparisons that help highlight progress made since the last report was published and the work that still needs to be done to better support those affected by the disease."

Seven years later, the Invisible Woman 2.0 Report is intended as an extension of the first report, based on results from the Patients and Carer Survey in 2019, a replication of the 2013 survey. This report aims to further explore the aBC patient landscape in Europe and provide clear comparisons that help highlight progress made since the last report was published and the work that still needs to be done to better support those affected by the disease.

Healthcare systems across Europe still vary considerably in terms of their capacity to provide equal high-quality care for all, with huge discrepancies in clinical outcomes and access for breast cancer patients[2]. By continuing to raise awareness of aBC and improving the understanding of its profound impact on women, their families and the wider society, we aim to equip policy makers and other stakeholders in Europe with the knowledge necessary to drive change for the benefit of patients and societies alike.

Fig.01 | A total of 98 respondents reached in 8 EU countries, majority of them are carers
30 minute computer assisted web interview (CAWI)

Fig.02 | Patient characteristics

Ketchum x

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Review

A multi-stakeholder approach in optimising patients' needs in the benefit assessment process of new metastatic breast cancer treatments☆

Fatima Cardoso[a,*], Nils Wilking[b], Renato Bernardini[c], Laura Biganzoli[d], Jaime Espin[e,f,g], Kaisa Miikkulainen[h], Susanne Schuurman[i], Danielle Spence[j], Sabine Spitz[k], Sonia Ujupan[l], Nicole Zernik[m], Jenn Gordon[n]

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[f] *CIBER en Epidemiología y Salud Pública / CIBER of Epidemiology and Public Health (CIBERESP), Spain*
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[h] *ICON Plc, Stockholm, Sweden*
[i] *ICON Plc, Stockholm, Sweden at the time of article submission*
[j] *Breast Cancer Network Australia, Australia*
[k] *Europa Donna, Vienna, Austria and European Patients' Academy on Therapeutic Innovation (EUPATI)*
[l] *Eli Lilly and Company, Brussels, Belgium*
[m] *Europa Donna, Paris, France*
[n] *Canadian Breast Cancer Network, Ottawa, ON, Canada*

A multi-stakeholder approach in optimising patients' needs in the benefit assessment process of new metastatic breast cancer treatments

Optimising patients’ needs in the benefit assessment process of new metastatic breast cancer treatments

Not all issues relevant to MBC patients are consistently considered in the current benefit assessment process of new treatments

Multi-stakeholder group was established to examine the **challenges** in current MBC treatment decision making processes and issue **key policy recommendations**.

This paper calls on decision makers to:
(1) Include MBC-specific patient priorities and outcomes in the overall benefit assessments of new MBC treatments; and
(2) Enhance multi-stakeholder collaboration in order to improve MBC patient outcomes.

BP37 Benefit assessment of new Metastatic Breast Cancer treatments – a multi-stakeholder approach

[1] Gordon J., [2] Bernardini R., [3] Biganzoli L., [4] Espin J.,[5] Miikkulainen K.,[5] Schuurman S.,[6] Spence D.,[7] Spitz S.,[8] Ujupan S.,[9] Wilking N.,[10] Zernik N.[11] Cardoso F.
[1]Canadian Breast Cancer Network, Canada; [2]University of Catania Medical School, Italy; [3] Brest Centre Hospital of Prato and European Society of Breast Cancer Specialists, Italy; [4] Andalusian School of Public Health, Spain; [5] ICON Access, Commercialisation & Communications, Sweden; [6] Cancer Council Victoria, Australia; [7]Europa Donna, Austria and European Patients' Academy (EUPATI), Austria and EU; [8]Eli Lilly & Company, Belgium; [9]Karolinska Institutet, Sweden, Hallands Hospital, Sweden; [10] Europa Donna, France; [11]Champalimaud Clinical Center/Champalimaud Foundation and ABC Global Alliance, Portugal

Background and aim

Metastatic breast cancer (MBC) is responsible for the majority of the 0.6 million deaths from breast cancer every year globally[1,2].There is a growing understanding, as science evolves that different cancer types require different approaches to treatment evaluation, especially for metastatic stages. MBC places a major humanistic and economic burden on patients and their caregivers, along with issues of equity in access to quality care. In an environment of scarce resource, the introduction of new MBC treatments may be hindered by several elements including the availability of relevant evidence for disease specific outcomes and the current benefit evaluation process through health technology assessment (HTA).

Therefore, in a multi-stakeholder collaboration, a White Paper was developed with the aims to place MBC on the agenda of national policy makers and provide consensus recommendations to the current challenges in the decision-making processes with respect to patient access to MBC treatment and care.

Results

A key finding was that the assessments of the overall benefit of MBC treatments are considered most valuable when informed by the disease specificities and MBC patients' needs and priorities. It was identified that not all attributes which are relevant to MBC patients are consistently considered in current decision-making.

The White Paper recognized that there is inherent value in multi-stakeholder engagement between patients, physicians, companies, and regulatory and HTA bodies; not least in providing support for timely patient access to transformative medicines and in the potential to improve patient outcomes. Two groups of recommendations were developed to tackle the identified challenges in MBC decision, one group of recommendations aimed at government agencies, HTA decision-makers and payers, and another group aimed at MBC multi-stakeholder groups. The overarching and detailed recommendations are outlined below.

Two overarching policy recommendations
GOVERNMENT AGENCIES, HTA DECISION-MAKERS AND PAYERS
MBC MULTI-STAKEHOLDER GROUPS

Overarching policy recommendation to government agencies, HTA decision-makers and payers: Include MBC-specific patient priorities and outcomes in the overall benefit assessment of new MBC treatments

- Incorporate MBC patient needs in the overall benefit assessment of an MBC treatment
- Provide an agreement on the appropriate endpoints in MBC, including the use of surrogate endpoints such as progression-free survival, with re-evaluation once overall survival data is available
- Ensure MBC patient involvement and, where relevant, voting rights in clinical assessments of MBC treatments both at national and /or regional levels
- Provide means to educate policy decision-makers on understanding the MBC patient needs
- Incorporate the value placed in delaying the start of chemotherapy in the overall benefit assessment, where applicable
- Support the development and incorporate MBC-specific Health Related Quality of Life and MBC-specific patient reported outcome (PRO) measures into decision-making and stablish one standardised MBC-specific PRO measure that is accepted and used by all HTA agencies
- Support and use observational data collection initiatives in MBC to acquire patient-level data for long-term outcomes
- Recognise and use Real World Evidence as supportive evidence in the overall benefit assessment of MBC treatments
- Recognise MBC patients' ability to return or maintain work or studies, and capacity to participate in daily activities as part of the overall benefit assessment of MBC treatments
- Consider objective value framework tools as one of the several sources of information in the decision making process to assess the clinical benefit of new treatments, such as the ESMO Magnitude of Clinical Benefit Scale (MCBS) or the ASCO Value Framework. These tools' methodologies are in constant update according to the experience in the field
- Address value in oncology by considering issues such as affordability and value based pricing, healthcare systems adaptability to the rate of innovation in cancer treatment, including waste and the wider healthcare spending

Overarching policy recommendation to MBC multi-stakeholder groups: Enhance multi-stakeholder collaboration in order to improve MBC patient outcomes

- Enforce the importance of multi-disciplinary specialized teams (MDTs) and Multidisciplinary Tumour Boards (MTBs) in MBC care
- Make sure all MBC patients are discussed in these boards
- Ensure the patient perspective is integrated into treatment guidelines and enforce the implementation of high quality, international and national MBC management guidelines
- Further promote MBC patient participation in formal early dialogues, integrated scientific advice engagements and (joint) clinical assessments in the EU and beyond
- Provide means and support initiatives to educate patients on understanding the general HTA processes

Conclusion

The White Paper raises the key finding that current assessment methodologies do not fully capture the patient relevant aspects of treatment benefit. Further collaboration between key stakeholder groups would allow for better consideration of MBC patient priorities, more informative choices in regards to trial designs and endpoints, with the support of Real World Data collection. In addition, collaboration would allow for MBC-specific PRO and patient reported outcomes measures (PROMS) development and allow early alignment on the requirements for the overall treatment benefit assessment in MBC to ensure that the needs of all key decision-makers are met. The further development of the overall benefit assessment of new treatments would greatly benefit from alignment between key stakeholders. The White Paper aims to promote multi-stakeholder collaboration in order to not only improve the MBC patient outcomes, but also the process to make treatments accessible to MBC patients around the world.

The alignment and multi-stakeholder engagement between patients, physicians, companies, and regulatory and HTA bodies would not only benefit patients, but also the health systems and society in general. The main findings and recommendations will be published soon in a peer-reviewed journal.

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2. GLOBOCAN, 2018. World factsheet. Available from: http://gco.iarc.fr/today/data/factsheets/populations/900-world-fact-sheets.pdf.

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Presented at the ABC5-Advanced Breast Cancer Fifth International Consensus Conference held on 14-16 November 2019, Lisbon, Portugal

Reference: 1. Fatima Cardoso et al. *Breast* 2020 Aug;52:78-87

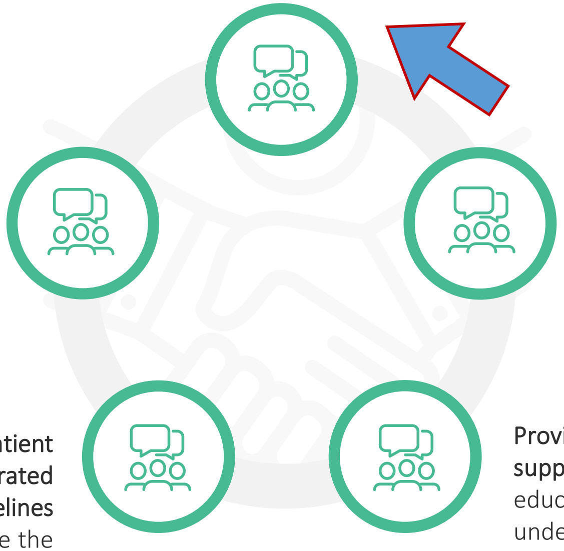
Eli Lilly and Company sponsored the literature review and provided financial support for meeting costs and materials produced by the Steering Committee but did not provide any fees to any of the members of the group for their involvement in this project. Although Eli Lilly and Company has provided comments on this document, the content of the final document reflects consensus from members of the Committee, who have full editorial control.

Key policy recommendations

Include MBC-specific patient priorities and outcomes in the overall benefit assessment of new MBC treatments

- Incorporate MBC patient needs in the overall benefit assessment of an MBC treatment
- Provide an agreement on the appropriate endpoints in MBC, including the use of surrogate endpoints such as progression-free survival, with re-evaluation once overall survival data is available
- Ensure MBC patient involvement and, where relevant, voting rights in clinical assessments of MBC treatments both at national and /or regional levels
- Provide means to educate policy decision-makers on understanding the needs of MBC patients
- Incorporate the value placed on delaying the start of chemotherapy in the overall benefit assessment, where applicable
- Support the development of and incorporate MBC-specific Health Related Quality of Life (HRQoL) and MBC-specific patient reported outcome (PRO) measures into decision-making and establish one standardised MBC-specific PRO measure that is accepted and used by all HTA agencies
- Support and use observational data collection initiatives in MBC to acquire patient-level data for long-term outcomes
- Recognise and use real-world evidence as supportive evidence in the overall benefit assessment of MBC treatments
- Recognise MBC patients' ability to return to or maintain work or studies, and capacity to participate in daily activities as part of the overall benefit assessment of MBC treatments
- Consider objective value framework tools as one of the several sources of information in the decision making process to assess the clinical benefit of new treatments, such as the ESMO Magnitude of Clinical Benefit Scale (MCBS) or the ASCO Value Framework. These tools' methodologies are constantly updated according to the experience in the field
- Address value in oncology by considering issues such as affordability and value-based pricing, and healthcare system adaptability to the rate of innovation in cancer treatment, including waste and the wider healthcare spending

Enhance multi-stakeholder collaboration in order to improve MBC patient outcomes



Make sure all **MBC patients are discussed** in these boards

Enforce the importance of multidisciplinary specialized teams (MDTs) and Multidisciplinary Tumor Boards (MTBs) in MBC care

Further **promote MBC patient participation in formal early dialogues**, integrated scientific advice engagements and (joint) clinical assessments in the EU and beyond

Ensure the patient perspective is integrated into treatment guidelines and enforce the implementation of high quality, international and national MBC management guidelines

Provide means and support initiatives to educate patients on understanding the general HTA processes

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Tackling gaps in breast cancer care

Panel 2 speakers

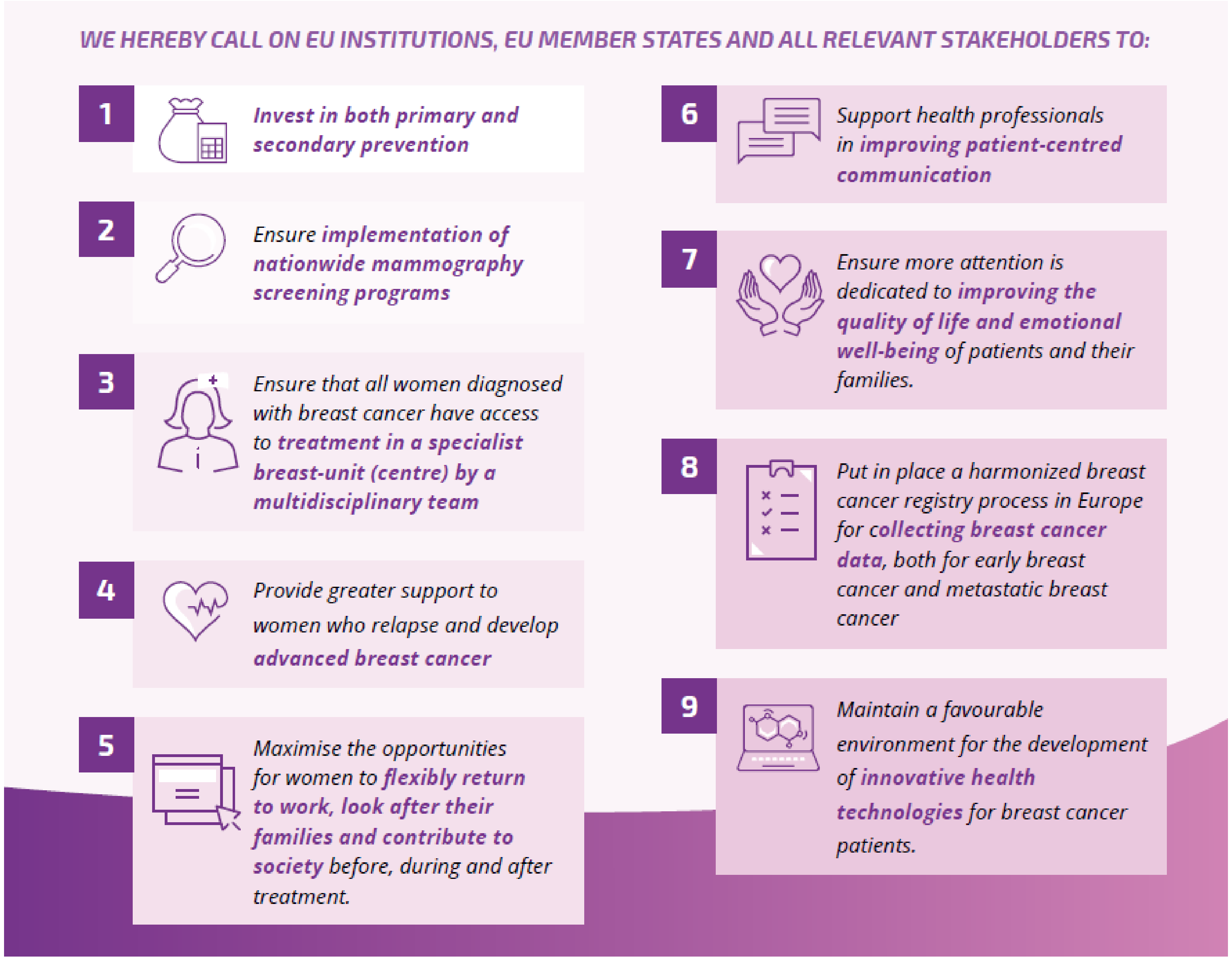
Ciarán Nicholl
Head of Unit, Health in Society,
JRC, European Commission

Alessandra Moretti
Member of the
European Parliament (S&D)

Isabel Rubio
President, EUSOMA and
President-elect, ESSO

#TBCTbridgethegap

Transforming Breast Cancer Together ‘Call for Change’



WE HEREBY CALL ON EU INSTITUTIONS, EU MEMBER STATES AND ALL RELEVANT STAKEHOLDERS TO:

1. ***Invest in both primary and secondary prevention***
2. *Ensure **implementation of nationwide mammography screening programs***
3. *Ensure that all women diagnosed with breast cancer have access to **treatment in a specialist breast-unit (centre) by a multidisciplinary team***
4. *Provide greater support to women who relapse and develop **advanced breast cancer***
5. *Maximise the opportunities for women to **flexibly return to work, look after their families and contribute to society** before, during and after treatment.*
6. *Support health professionals in **improving patient-centred communication***
7. *Ensure more attention is dedicated to **improving the quality of life and emotional well-being** of patients and their families.*
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*
9. *Maintain a favourable environment for the development of **innovative health technologies** for breast cancer patients.*

Transforming Breast Cancer Together

Thank you!

ABC GlobAlliance

European Cancer Patient Coalition

Lilly

European School of Oncology
learning to care

esso
The European Society of Surgical Oncology

EUROPA DONNA
The European Breast Cancer Coalition

EUSOMA
European Society of Breast Cancer Specialists

HELSINN
Building quality cancer care together

NOVARTIS

Roche

WORKING WITH CANCER