

Challenge Backgrounder



This global challenge seeks to close the gaps in mBC care and catalyze the development of meaningful solutions to support patients along the care continuum and improve their overall quality of life. This opportunity is open to developers, entrepreneurs, designers, and innovators around the world to develop integrated solutions that empower patients living with mBC.

Can you develop disruptive, technology-enabled solutions to help enrich the lives of patients living with metastatic breast cancer (mBC)?

mBC Clinical Information

Metastatic breast cancer (mBC) is the stage of breast cancer at which the tumor has spread beyond the breast to other organs in the body.^{1,2} Also known as advanced breast cancer (aBC), stage IV breast cancer, or secondary breast cancer, mBC cannot currently be cured and is attributable to the majority of breast cancer deaths around the world.^{3,4,5} Furthermore, the number of deaths due to mBC is projected to increase by 43% over the next 15 years.⁶

Breast cancer is the most common invasive cancer in women with an estimated 1.7 million new cases diagnosed in 2012 worldwide.^{3,5} While great progress has been made in the management of breast cancer, it remains a significant global health issue.⁵ Between 2008 and 2012, breast cancer incidence (rate of new breast cancer cases) increased while mortality rates remained relatively stable, as suggested by the Global Burden of Cancer Study (GLOBOCAN) data from more than 180 countries.^{6,7}

Generally speaking, breast cancer can be divided into 3 broad subgroups based on cell receptor expression.^{8,9} These categories include hormone receptor-positive (HR+), indicating the presence of either estrogen (ER+) and/or progesterone (PR+) receptors; human epidermal growth factor receptor-2-positive (HER2+); and triple-negative breast cancer (TNBC), indicating that there is no detectable expression of PR, ER, or HER2.^{8,9} The overwhelming majority of breast cancers are classified as being HR+, with HER2+ and TNBC each accounting for less than 15% of all breast cancer diagnoses in the United States.⁸ These receptors act as biomarkers and are both prognostic (indicating the likely course of the disease) and predictive of targeted therapy response, with clinical outcomes such as time to recurrence and overall survival (OS) differing by subtype in patients with mBC.^{10,11,12} For instance, though median survival after mBC diagnosis is approximately 2-3 years, patients with TNBC have the shortest median OS of around 10 months compared with 30-40 months for those with HR+ or HER2+ disease.^{13,14}

mBC is a clinically complicated, heterogeneous disease with multiple treatment choices potentially available. However, the daily needs of patients with mBC are consistent across subtype.¹⁵ In the absence of a cure, mBC currently requires life-long treatment, with the goal of maximizing survival time and quality of life.¹⁶ Patients with mBC face complex decisions throughout the course of their care and are presented with numerous treatment options, including chemotherapy, targeted therapy, surgery, radiation therapy, and participation in clinical trials. Recent advances in care have been unequal across mBC subtypes.^{17,18} Notably, although the first endocrine therapies for breast cancer were directed at the HR+ subtype in mBC, in the past decade, most treatment innovations have been for HER2+ breast cancer.^{4,8,19} Despite these and other innovations, 5-year survival rates for mBC have remained low at approximately 25%.^{1,2} As such, moving forward, the treatment paradigm is evolving to a personalized approach for each patient, with aspirations to change mBC into a chronic disease with long-term remissions.

Pfizer Oncology's Commitment to Patients with mBC

Based on the limited understanding of the needs surrounding patients with mBC, Pfizer Inc., working collaboratively with the European School of Oncology (ESO) and within the scope of the Advanced Breast Cancer Third International Consensus Conference (ABC3), commissioned The *Global Status of Advanced/Metastatic Breast Cancer 2005-2015 Decade Report*²⁰ to better understand the unique needs of patients living with mBC. This report is the first globally-focused assessment of mBC across the care continuum as well as the political, economic, societal, and scientific landscapes. It reveals both improvements over the past decade and substantial, continuing gaps in care and support. The report also highlights that there have only been incremental improvements in treatment outcomes for patients with mBC.¹⁵ Insights from this report have been outlined below to provide an overview of the current global status of mBC.

Key attributes and needs of patients with mBC

Diagnosis

While some patients initially are diagnosed with metastatic disease, the majority are diagnosed following an earlier diagnosis of breast cancer that has developed into metastatic disease.^{4,21} Though statistics vary widely by country and economic status, globally:

- Approximately 5-10% of newly diagnosed breast cancer patients will present with metastatic disease.³ Specifically, in high-income countries, less than 8% of breast cancer patients are initially diagnosed with metastatic disease compared with 50-80% in most low- and middle-income countries²²
- Globally, of the patients diagnosed with early breast cancer (eBC), 20-30% on average are anticipated to eventually develop metastatic disease; however, this can vary dependent on socio-economic status²¹

The diagnosis of mBC often represents a time of shock, crisis, and anxiety for patients and their families.²³ Those patients who are recurrent may also suffer from high emotional burden as they have previously experienced "survivorship" with their disease.¹⁵

“ Although I stay as positive as possible, there is always the horrible doubt of ‘what if’ and ‘when.’ ”

mBC Patient, from Secondary Breast Cancer Research, BCNA, 2014¹⁵

Median survival for mBC is an estimated 2-3 years; however, this can vary greatly among patients dependent on mBC subtype and other patient characteristics. Some patients can live with their disease for several years longer.^{1,23,24} This indefinite prognosis can leave patients and their families experiencing high levels of uncertainty and significant emotional burden.^{15,25}

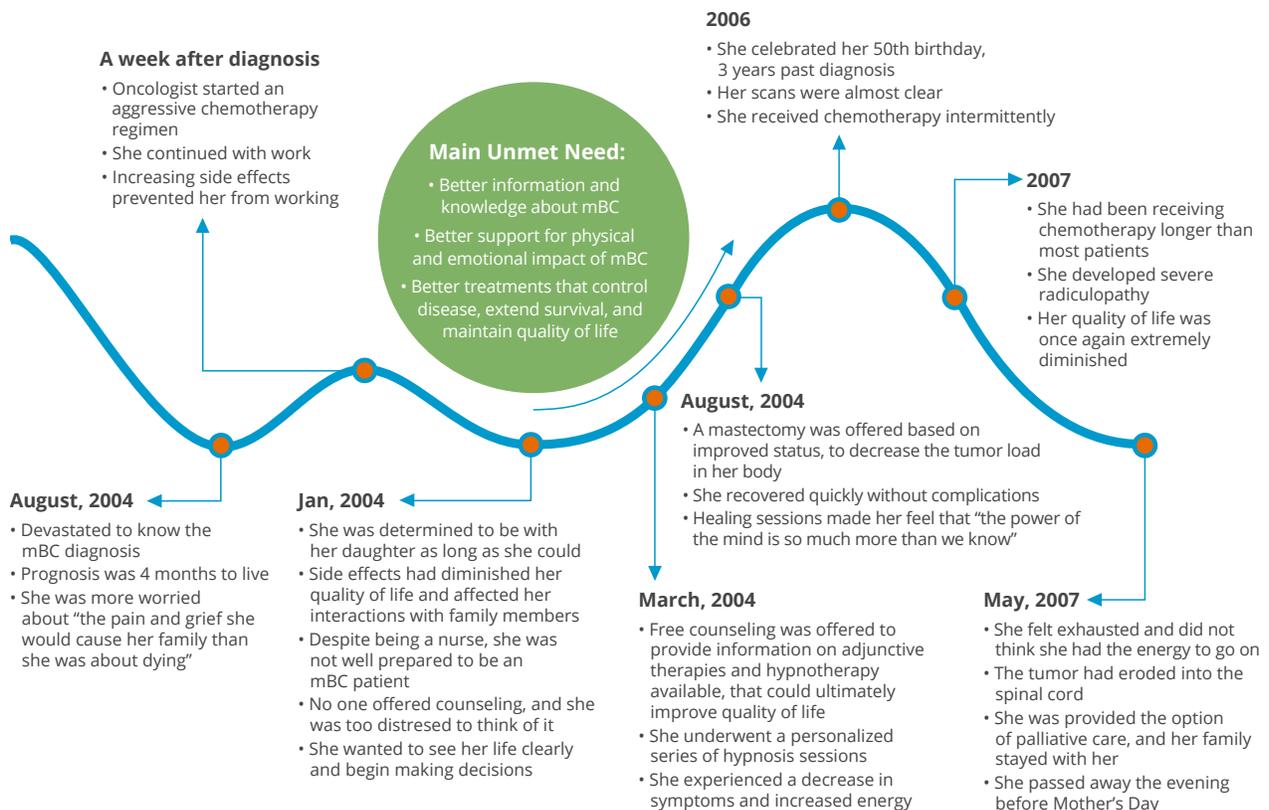
The mBC Care Continuum

When diagnosed with mBC, patients undergo a number of different challenges as they move through a series of highs and lows along the disease continuum (see Figure 1).^{15,26} mBC does not follow a set path from diagnosis to end of life, and the amount of time in each stage is relatively unknown. This results in a high level of uncertainty as patients and their families continuously make treatment decisions as the disease progresses. In turn, this can lead to both emotional and psychological burden on patients and their families. Patients may feel confused, overwhelmed, or uncertain when asked to make so many difficult decisions, particularly when evaluating treatment side effects and quality of life. The constant demand for such discussions may prevent patients from feeling comfortable in their decisions, or unable to ask the relevant questions, at that particular stage of their disease.¹⁵

Figure 1: Highs and Lows of the mBC Patient Experience^{15,26}

Global Status of Advanced/Metastatic Breast Cancer 2005-2015 Decade Report

Based on personal journal notes from a 47-year-old female, US, nurse with mBC



Multidisciplinary Care Needs

Throughout the care continuum, patients with mBC face increasingly complex decisions regarding treatment choices and care goals.¹⁵ Because of these complicated considerations, patients must rely on a multidisciplinary healthcare team in order to feel fully supported. An mBC care team often consists of a full range of healthcare professionals beyond the oncologist and nurse, such as a psychiatrist, nutritionist, palliative care specialist, or nurse navigator. These specialists are essential in creating a comprehensive approach to care management that considers every aspect of patient well-being while being treated for mBC and addresses their very specific needs.²⁴

Despite the need for this multifunctional healthcare team, not all healthcare systems have established the infrastructure and services to support mBC care delivery, particularly related to psychosocial support and continuity of care.¹⁵

Burden on Daily Life

Although mBC can affect both men and women, approximately 99% of patients with mBC are women, most commonly in middle to late stages of life.²⁷ Many patients may be responsible for organizing and running their households, caring for their families, including parents and younger children such as grandchildren, as well as maintaining a job. The impact of the disease and its treatment may hinder patients' ability to complete daily tasks such as driving to work or school and maintaining the home.¹⁵ As such, patients with mBC may require assistance with these daily tasks that they were previously able to complete with ease.¹⁵

**“ People don't understand the word metastatic to begin with...
And when I'd tell them I was stage IV, they'd give me pity
or stay away or see me a year later and think I was a ghost.
They couldn't believe I was alive. ”**

US mBC patient, fredhutch.org, 2014¹⁵

Misperceptions of mBC

“ People would rather have AIDS than cancer; they know that they can survive AIDS but do not think they can survive cancer...in Zambia, cancer equals death. ”

Udie Soko, Cofounder and Executive Director at the *Zambian Cancer Society*, Zambia, 2015¹⁵

mBC also is associated with many misperceptions and cultural stigmas, often directly impacting patients living with the disease.^{15,28} In a global survey, 48%-76% of the general population believed that advanced breast cancer is curable. Furthermore, on average, 28% of the general population indicated that patients with mBC should keep it a secret and not discuss it with anyone.¹⁵ Some believe that patients are diagnosed with mBC if they have not been taking preventative measures, such as correctly taking medications.¹⁵ Such misperceptions may be caused by the strong focus on early-stage disease and survivorship.¹⁵ These extreme perceptions of mBC result in patients experiencing social rejection, isolation and feeling misunderstood, particularly within the breast cancer community.¹⁵

“ [Our] goal is to make sure that the voices of women living with mBC are heard during Breast Cancer Awareness Month because so much is going on and most of it relates to early stage: ‘Let’s look for a cure.’ ‘Treatment is better.’ ‘Diagnosis is better.’ But there’s still a large number [of patients] who are becoming metastatic. ”

US Patient Support Organization¹⁵

Unmet Needs of Patients with mBC

The *Global Status of Advanced/Metastatic Breast Cancer 2005-2015 Decade Report* identified a series of unmet needs that patients with mBC face. Some of the key unmet needs across the disease continuum include¹⁵:

- Patients living with mBC need comprehensive, individualized, compassionate and culturally sensitive dialogue with their doctors, which can support shared decision-making
- The far-reaching effect of mBC on patient quality of life is not yet adequately measured and addressed. There is a need for greater focus and research into the factors that impact quality of life and effective psychosocial interventions to maximize this measure in patients living with mBC
- Patients living with mBC need multidisciplinary, comprehensive approaches to care, with greater focus on support outside of treatment decision-making
- There is a need for greater public understanding about mBC and what the diagnosis really means in order to address patients' feelings of isolation or stigma
- Patients living with mBC and their families need more tailored and relevant information regarding their specific disease from their healthcare provider team

With the current state of mBC in mind, Pfizer would like to take the next step towards advancing care for this patient group including addressing their unique challenges. Pfizer hopes that through the development of a worldwide innovation challenge, the innovation community* and mBC community will work together to develop solutions that will further meet the complex and unique needs of patients with this disease.

*The "innovation community" includes entrepreneurs, designers, developers and healthcare professionals who seek to develop new approaches and solutions to tackle issues in health and improve care delivery.

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