

Metastatic breast cancer patients: addressing their unmet needs

MBC Advocacy Working Group

In the United States, approximately 30% of women diagnosed with early-stage breast cancer will ultimately develop metastatic disease. Yet patients living with metastatic breast cancer (MBC) report feeling isolated in terms of the attention, support, and care they receive, compared with women with earlier stage breast cancer. For women with advanced disease, it's critical to have access to the resources and support services that have so benefited patients with early breast cancer. A group of patient advocates is determined to see that these needs are met. Its report and a commentary from William J. Gradishar, MD, FACP, recognized internationally for his work in this field, are detailed here. In upcoming issues of *Community Oncology*, we will present articles addressing the clinical challenges of treating drug-resistant MBC.

Early in 2008, 16 patient advocates from seven countries met in New York City to talk about better addressing the unmet needs of women with metastatic breast cancer (MBC).

Sponsored by Pfizer Oncology, the MBC Advocacy Working Group compiled a consensus report with the input of more than 30 women living with the disease and the support of Musa Mayer from AdvancedBC.org and William J. Gradishar, MD, FACP, director of breast medical oncology at the Robert H. Lurie Comprehensive Cancer Center. This is its report and recommendations.

Breast cancer is the leading cause of cancer death among women worldwide. Globally, there are an estimated 4.4 million women who have been diagnosed with breast cancer within the past 5 years.¹ In developed countries, 30% of women with earlier stages of breast cancer will eventually be diagnosed with metastatic disease.² In developing countries, the majority of women with breast cancer are diagnosed with advanced-stage disease.³

The exact proportion of those living with MBC is unknown, as these data are not collected. Data collection of MBC prevalence and survival rates is essential to assess recent advances in treatment, and to determine areas where additional research is needed.

Compared with women with earlier stage breast cancer, women living with MBC report feelings of isolation in regard to the attention, support, and care they receive. Awareness initiatives that educate the public and dispel misconceptions are essential in decreasing the marginalization of the MBC community.

As women are living with MBC for longer periods, the need for programs and services specific to

MBC is becoming increasingly important.

Women with MBC have unique characteristics and needs that differ from those in the broader breast cancer community, and the same resources are often not appropriate for them. Further, within the MBC community, women often have varied experiences. According to women with MBC, there are not enough information and support services specific to advanced disease, and some find it difficult to locate and access existing materials.

Given the need for additional treatment options for MBC, clinical trial information and services are critical but largely underutilized. Further, women with MBC who are eager to participate in clinical trials may face enrollment barriers due to restrictive design protocols. Although a majority of cancer patients report being receptive to enrollment, accrual to breast cancer clinical trials remains low.⁴ There are likely many reasons for this, but major contributors include negative misconceptions, lack of access to appropriate information, and difficulty in understanding clinical trial materials. Clinical trials that exclude previously treated patients or certain metastases may decrease the chances for women with MBC to be eligible for enrollment.

Given this situation, we are prioritizing the following three areas for immediate action:

- Improve access to tailored information, resources, and support services for women with MBC.
- Focus attention on the MBC community. Create a unified voice and platform that speaks to its unique needs.
- Increase understanding of and access to clinical trials.

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This report is a call to action for advocacy groups, industry, healthcare professionals, government, academia, community/religious organizations, and all other relevant breast cancer stakeholders to begin implementation of the following strategies as appropriate in each country setting.

Improve access to information, resources, and support services

Solicit registries, government, academia, and industry to collect data on the prevalence, incidence and current survival rates of MBC to understand the proportion of those living with the disease and to investigate changes in prognosis in this patient group.

Create tailored support and information resources that are relevant to the diverse experiences of women within the MBC community.

Offer on-line, telephone and/or in-person support groups and information resources that are specific to different subsets of women with MBC, for example, by age, race, site of metastases, hormone status, and timing of advanced-disease diagnosis (eg, initial versus recurrent). Offer culturally relevant materials.

Provide information on existing and emerging treatment options, including clinical trial data and clinical practice guidelines, as well as symptom and side-effect management.

Prepare women for what to expect following treatment for MBC; offer materials that focus on topics such as “chemo brain,” post-treatment fatigue, and the role of nutrition and exercise in disease management.

Increase collaboration and information sharing of resources for women with MBC in an effort to provide greater access to information.

Create centralized Web-based and off-line venues that house information on MBC to help organize and streamline the information-gathering experience.

Coordinate interactive research-focused conferences and workshops that

provide women with MBC access to other patients as well as leading physicians who can provide updates on the latest research and treatment options.

Ensure MBC-specific information is integrated into the agendas of existing general breast cancer conferences/forums.

Create an infrastructure for healthcare professionals to provide accurate clinical information as well as psychological and practical support, including financial, legal, and end-of-life guidance, from the point of diagnosis onward and throughout the duration of the illness.

Encourage healthcare institutions to initiate MBC patient-support programs such as patient navigator or case management programs and key worker services to improve a patient’s experience in the healthcare system upon diagnosis and throughout treatment.

Educate women completing treatment for primary breast cancer about the signs and symptoms of MBC. Ensure that healthcare providers are properly trained to recognize the signs of disease progression.

Focus attention on the MBC community

Educate the public and the larger breast cancer community about MBC and the need for increased attention and resources. Implement programs such as designating a specific day or week for MBC awareness.

Assist and support women with MBC interested in speaking out and sharing their personal experiences within their communities. Seek publicity and promotional opportunities to raise the profiles of these women, as appropriate. Identify and work with public figures who can help raise awareness on a national level and give a much needed voice to women with MBC.

Shift the dialogue to be more positive when speaking about MBC.

Begin talking about metastatic disease as a long-term illness that can be managed in some cases.

Sensitize healthcare professionals to

use language that avoids contributing to MBC women’s feelings of guilt, anxiety, and fear that they failed or should have done things differently.

Increase understanding of and access to clinical trials

Initiate guidelines requiring healthcare providers to communicate the option of clinical trials at the time of first diagnosis, when most women with MBC actively seek information.

Assist women with the decision-making process to ensure they are making an informed choice by discussing the benefits and potential risks while dispelling common misconceptions.

Create an up-to-date, user-friendly listing of all available clinical trials for MBC.

Develop materials that will help women better understand the terminology associated with clinical trials. For example, extend access to a clinical trial glossary of terms and frequently asked questions/answers. Trial sponsors should create easy-to-read clinical trial cards that clearly communicate quality-of-life endpoints and trial locations.

Provide one-on-one support for women throughout the enrollment process, including assistance with informed consent documents, transfer of medical records, and follow-up correspondence. Implement support systems for patients enrolled in clinical trials, including trial support groups and check-in calls from nurses and/or social workers.

Increase communication about compassionate use/expanded access programs to women who are not eligible for an MBC clinical trial.

Design clinical trials that include underserved segments of the MBC community, such as heavily pretreated women and women with certain metastases.

As an increasing number of women live with MBC for longer periods, many more people are in need of support and information on MBC. Unique information and support services are critical, and as breast cancer advocates, we need to develop and

MBC Advocacy Working Group

The MBC Advocacy Working Group was established with sponsorship from Pfizer Oncology and represents the opinions of more than 30 women living with metastatic breast cancer who participated in reviews of the statements and strategies put forth in this report:

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- Vitoria Herzberg, ABCANCER (Brazil)
- Carla Howery, MA, Patient Advocate (US)
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- Susan Knox, Europa Donna – The European Breast Cancer Coalition (Head Office, Italy)
- Stacy Lewis, Young Survival Coalition (US)
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- Alejandra Mijares de Capín, Grupo Reto (Mexico)
- Jennifer Paradis, Breastcancer.org (US)
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- Donna Sheehan, Willow Breast Cancer Support (Canada)
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position future initiatives.

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Commentary

Supporting patients with metastatic breast cancer: a call to action

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Women with metastatic breast cancer (MBC) have unique needs. As patients, they have already surmounted emotional and physical hurdles in their fight against early disease; often, they feel psychologically vulnerable. So when they are told that their disease has metastasized, they experience anxieties and fears as their care shifts from being potentially curative to palliative. Providing psychological support is critically important.

A key item emphasized in the accompanying consensus report was the need to give patients more information about clinical trials and to improve access for those who fit entry criteria. Eighty percent of cancer clinical trials in the United States are delayed due to incomplete enrollment, but most patients are unaware that these trials even exist or are put off by restrictive trial designs and consent forms that are difficult to understand.¹ Of the patients seen in the clinic, only 2%–4% participate in trials.² At the same time, there has been a dramatic increase in the number of drugs entering clinical trials. In the United States alone, 30,000 patients are needed to enroll in phase III trials on advanced breast cancer.³ The result is a crisis in the drug development process.

What can we, as clinical oncologists, do to heighten awareness of MBC?

- We should be calling for improvements in the quality of the support that is offered to patients with MBC, to bring us in line with the support services available in the early-stage setting.
- We should be proactive in our discussions about clinical trials and provide ongoing support to patients throughout the enrollment process.
- We should begin communicating this information in the consulting room and tailor it so that the right information can reach the right woman regardless of the stage of her disease.

We are at a crossroads in providing care to patients with MBC. As healthcare providers, we are obligated to communicate openly with these patients and to work with advocacy groups to allow access to information on the disease. By addressing the unmet needs of women with MBC, we hope they can make informed decisions about their lives that will support them in their treatment journey.

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MBC treatments in use and in the pipeline

THE INTRODUCTION of novel systemic and targeted treatments has meant that women with breast cancer are now living longer with metastatic disease. The choice of therapy for metastatic breast cancer (MBC) depends on a number of factors, including disease characteristics and the treatment preferences of the physician and patient. Ultimately, the goal of therapy is to prolong progression-free survival for as long as possible, palliate, and maintain

patients' quality of life.

Systemic treatments for MBC include chemotherapy, endocrine therapy, and newer targeted therapies. Such targeted treatments include the antivascular endothelial growth factor monoclonal antibody (mAb) bevacizumab (Avastin), plus paclitaxel, a standard of care for patients with human epidermal growth factor-2 (HER2)-negative disease. For HER2-positive patients, a standard of care is the anti-HER2 mAb tras-

tuzumab (Herceptin), plus a taxane. In addition, there are numerous combinations of chemotherapy and endocrine therapy that could be considered for patients with refractory disease. A variety of new targeted agents are being investigated in MBC trials, including antiangiogenic agents (ie, sunitinib [Sutent], sorafenib [Nexavar], and pazopanib), mTOR inhibitors (ie, everolimus), and heat shock protein 90 inhibitors (ie, tanespimycin).