

IMPROVING SUPPORT IN TREATMENT DECISION MAKING FOR PATIENTS WITH METASTATIC BREAST CANCER

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ABSTRACT

Breast cancer is the most common noncutaneous cancer in women in the United States. Despite decades of progress and improved outcomes for patients with early-stage breast cancers, it has been estimated that almost a third of patients will be diagnosed with advanced or metastatic disease. To better understand the unique experiences of patients with metastatic breast cancer (MBC), a group of directors and social workers from CancerCare conducted a roundtable discussion that included 5 patients with MBC and 3 of their caregivers; the roundtable was attended by a member of the Young Survival Coalition. The discussion identified several important areas in which focused education of patients, caregivers, and health care providers could improve the treatment experience of patients with MBC. In addition, findings from the roundtable also identified the need for targeted support for patients with MBC and their caregivers, distinct from support for patients with early-stage disease. Based on these findings, we propose recommendations to improve the treatment experience of patients with MBC and their caregivers.

INTRODUCTION

On November 12, 2019, a group of directors and social workers from CancerCare met with 5 patients who had been diagnosed with metastatic breast cancer (MBC) and 3 of their caregivers. The objectives of this roundtable were to characterize patients' experiences starting and continuing treatment for MBC, to understand the steps and knowledge needed for informed decisions about care, and to identify gaps and opportunities to better support patients in making decisions about treatment for MBC. Discussions from the roundtable led to the development of this white paper focused on the experience and decision-making process that patients go through leading up to and through treatment for MBC. Herein, we identify opportunities for improving care for patients with MBC throughout the treatment journey and provide recommendations to improve the experiences of patients and caregivers.

MBC Represents a Significant Burden of Disease in the United States

In the United States, estimates are that more than 260,000 new cases of invasive breast cancer were diagnosed in women in the year 2019, making breast cancer the most commonly diagnosed noncutaneous cancer in women. Incidence of breast cancer has been increasing slowly over time, growing at a rate of 0.4% per year between 2006 and 2015. Despite this increase in incidence, the rate of mortality associated with female breast cancer declined by 40% from 1989 to 2016, resulting in 348,800 fewer

deaths than would have been expected if the death rate had remained stable.¹

Decreased mortality is likely due to improvements in early detection and more effective treatment of breast cancers, as 62% of patients with breast cancer are diagnosed at the localized stage, which is associated with a 5-year overall survival rate of 98.8%.

However, there is still room for progress, as 30% of patients are diagnosed with regional lymph node involvement and 6% with distant metastases (Figure 1).² Furthermore, recurrent advanced or metastatic breast cancer (MBC) has been estimated to occur in as many as 30% of patients.³ Because patients with distant metastases at diagnosis have a 5-year relative survival rate of only 27.4%,² advances in the management and treatment of MBC are needed to continue to improve patient outcomes.

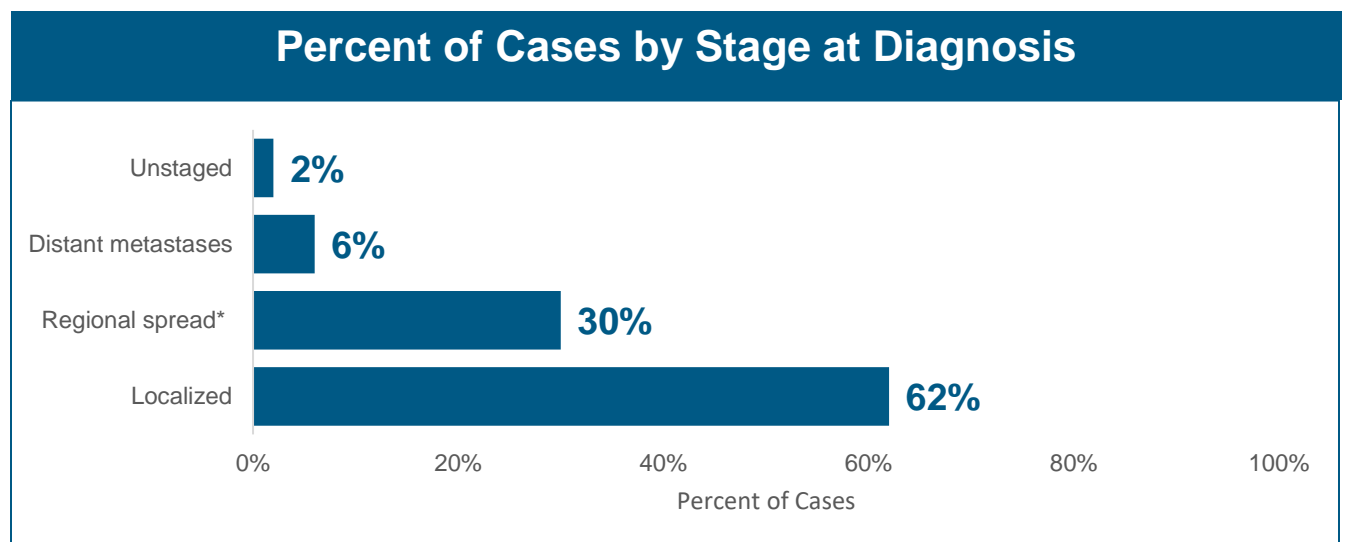


Figure 1. Percentage of female breast cancer cases by stage at diagnosis.²

*Spread to regional lymph nodes.

Breast cancer is most commonly diagnosed in women aged 55 to 64 (Figure 2A), and the median age at diagnosis is 62.^{2,4} Incidence of breast cancer is higher among non-Hispanic white women and non-Hispanic black women compared with other racial/ethnic groups (Figure 2B), and non-Hispanic black women experience the highest rate of mortality.⁴ Proposed contributors to racial disparities include differences in screening rates, as well as racial differences in the frequencies of specific breast cancer subtypes. For example, black women are more likely to be diagnosed with triple-negative breast cancer, a more difficult-to-treat subtype.⁵ In addition to sex, age, and race, other risk factors associated with development of breast cancer include a long menstrual history, nulliparity or having children after age 30, high levels of sex hormones, and recent use of oral contraceptives. Inherited mutations in the breast cancer susceptibility genes *BRCA1* and *BRCA2*; some benign breast conditions, such as atypical hyperplasia; a history of ductal or lobular carcinoma in situ; high breast tissue density; and high-dose radiation to the chest at a young age are also associated with increased risk for breast cancer.¹ Protective factors include breastfeeding for at least 1 year; exercise; early pregnancy; and use of estrogen after hysterectomy, selective estrogen receptor modulators, or aromatase inhibitors or activators.^{1,6}

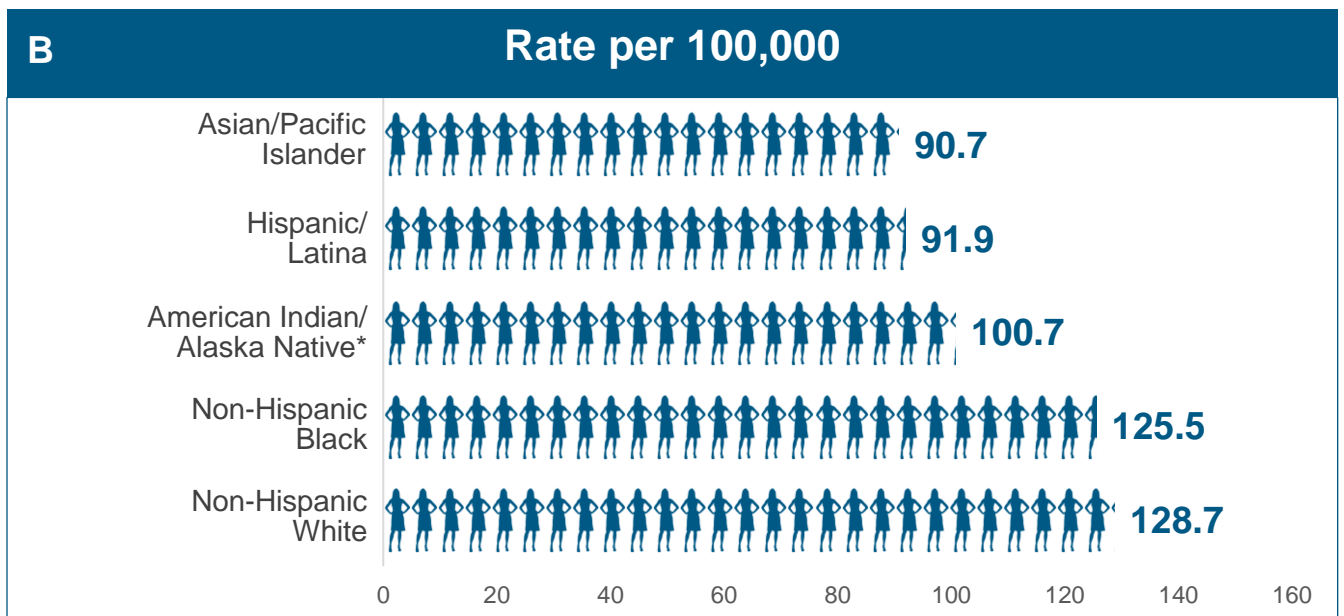
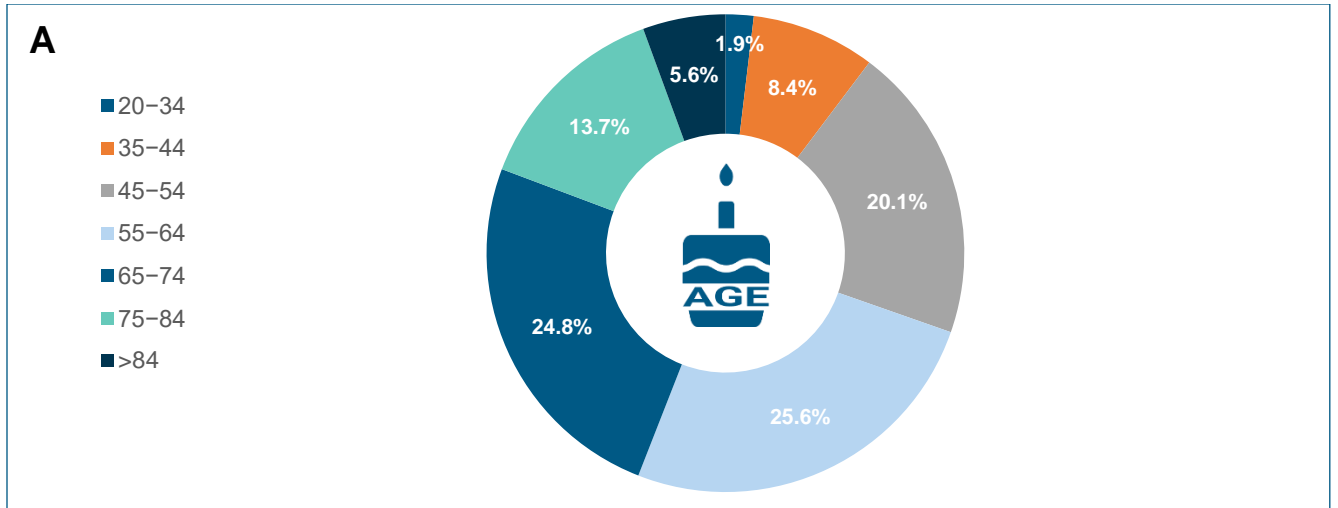


Figure 2. Demographics of patients with breast cancer. A. Incidence by age.²

B. Incidence by race/ethnicity.⁴

*Statistics based on data from Contract Health Service Delivery Area counties. Note: Rates are age adjusted to the 2000 US standard population

Changes in Screening, Diagnosis, and Treatment Have Improved Outcomes for Patients With Breast Cancer

Much of the improvement in breast cancer survival rates over the last few decades can be attributed to improved screening and increased symptom awareness.¹ Screening mammography has been associated with a survival benefit among women aged 40 to 69, and guidelines developed by the American Cancer Society recommend regular screening for women with average risk of disease age 45 and older and the opportunity for screening for women aged 40 to 44.⁷ However, despite the benefits of screening mammography, some breast cancers are more challenging to identify by mammogram. False-negative results are more common with mucinous and lobular cancers, in patients with dense breast tissue (more common in younger women), and with rapidly growing tumors that become detectable during the interval between examinations.⁸ For patients at high risk for disease, including women with *BRCA* mutations, earlier screening and use of breast magnetic resonance imaging (MRI) as an adjunct to mammography is recommended.⁹

Upon a positive screening test result, breast cancer diagnostic confirmation may involve mammography, ultrasound, breast MRI, and/or biopsy. After diagnosis and clinical staging, patients and their health care providers (HCPs) must make decisions about treatment. Factors contributing to prognosis and selection of therapy include menopausal status, cancer stage and grade, hormone receptor (estrogen receptor, progesterone receptor) status, human epidermal growth factor receptor 2 (HER2)

status, molecular profiling, and breast cancer subtype.⁶ Breast cancers can be classified into distinct subtypes according to the level of invasion into the surrounding breast tissue and histology. Ductal carcinoma in situ (or intraductal carcinoma) is a localized cancer that has not invaded the surrounding tissues. In contrast, invasive (or infiltrating) breast cancers, including invasive ductal carcinoma and invasive lobular carcinoma, are cancers that have spread into the surrounding breast tissues. Other, more aggressive subtypes of invasive breast cancers include triple-negative breast cancer, which comprises approximately 15% of breast cancers, and inflammatory breast cancer, which accounts for 1% to 5% of breast cancers.¹⁰

Standard treatment for early, localized, or operable cancers (stages I-III A and operable IIIC) may include lumpectomy or mastectomy, postoperative radiation therapy, and pre- or postoperative systemic therapies. Preoperative options for systemic therapy include chemotherapy, HER2-targeted therapy, or endocrine therapy; postoperative options include tamoxifen, aromatase inhibitor therapy, ovarian function suppression, and chemotherapy.⁶ In addition to these options, treatment for MBC may include treatment with targeted therapies, including inhibitors of mammalian target of rapamycin (mTOR), cyclin-dependent kinase 4/6 (CDK4/6), or phosphatidylinositol-4,5-bisphosphate 3-kinase catalytic subunit alpha (PI3K α); bone-modifying therapy; and immunotherapy.^{6,11} Patients with MBC should also consider enrolling in ongoing clinical trials of investigational agents.⁶

Patient Needs Vary Throughout the Treatment Journey

Effective treatment of MBC requires holistic management of the patient's physical, social, psychological, and emotional needs.¹² These needs may change throughout the treatment journey and can also vary based on the unique characteristics and circumstances of each patient, including age and income.^{12,13} For optimal patient-centered management, education is an important aspect of care, and patients should be educated about their chances of recovery, benefits and disadvantages of treatments, the availability of supportive care, and financial considerations before and during treatment.¹² Caregivers play a critical role in providing emotional support for patients, and, therefore, supporting the needs of caregivers is another important aspect of high-quality patient care.¹⁴

To provide a platform for addressing these needs, the Institute of Medicine recommends sharing a document containing the treatment plan with patients and caregivers as a part of patient-centered cancer care. This document should include information about staging, diagnosis, and relevant biomarkers; a summary of the initial treatment plan; a list of common and rare toxicities associated with treatment, as well as any expected long-term effects; information for HCPs in charge of treatment; psychosocial and supportive care plans; documentation of any vocational, disability, or financial information; and advanced care directives. A well-developed treatment plan created with collaboration between the patient, caregiver, and a multidisciplinary care team can

benefit patients and caregivers by promoting comprehension and retention, managing expectations and anxiety, and providing continuity of care.¹⁵

Despite the growing emphasis on the importance of patient-centered cancer care throughout the treatment journey, progress in breast cancer policy has largely been skewed toward disease awareness and other early parts of the patient experience, leaving patients with MBC largely underserved. A global analysis previously identified access to novel treatments for MBC, to ongoing support, and to well-coordinated care as important challenges for these patients.¹⁶ To better understand the unmet needs of patients with MBC in the United States, on November 12, 2019, a group of directors and social workers from CancerCare met with 5 patients with MBC and 3 caregivers to discuss MBC care. The section below summarizes findings from this MBC Roundtable in order to identify key gaps and highlight opportunities and recommendations for the care of patients with MBC.

FINDINGS FROM THE MBC ROUNDTABLE

Participants

Participants included 5 women diagnosed with MBC and 3 caregivers. Two patients were initially diagnosed with MBC, and 3 patients were originally diagnosed with early-stage breast cancer and progressed to MBC. Patients were diagnosed with a range of subtypes. Although 1 patient presented with a more generalized symptom, specifically back pain, the other 4 patients originally presented with breast cancer after identifying a

lump during self-examination of their breasts. For some patients, mammography did not locate the lump, consistent with reported challenges in detection of lobular breast cancer by mammography.

Patient experiences and education at diagnosis vary widely

Discussion of the patient experience at diagnosis revealed that patients had limited knowledge about MBC prior to their diagnosis. In fact, in some cases, patients who were treated for early-stage breast cancer were unaware that their cancers could progress to MBC. One roundtable participant attributed onset of bone pain to a side effect of treatment, but later learned that the pain was a result of bone metastases. Because of the nonspecific nature of some symptoms of MBC, patients initially diagnosed with early-stage breast cancer may mistake symptoms of MBC, which can make diagnosis of progression more difficult.¹⁷ Based on this important need for patient education, we recommend educating patients about the risk of progression from early-stage breast cancer to MBC, with an emphasis on how to recognize signs of progression.

Patients were informed of their diagnoses through a number of different mechanisms, including at doctor appointments with family members present and over the phone while at work. Caregivers and family members were often present at the diagnosis for support or to gather information. The emotional toll was difficult for caregivers and for patients, who reported worrying about how their diagnosis would affect family members.

Diagnostic information was communicated by a variety of HCPs, ranging from primary care providers to oncologists and breast surgeons. Patients voiced a desire for more information about MBC and treatment options at diagnosis. They reported that either the information was not provided to them or that they were too overwhelmed, potentially leading to a lack of retention.

Consistent with the experiences of these roundtable participants, diagnosis with breast cancer has been reported to lead to feelings of distress and grief, as well as loss of control, which may prevent some patients from absorbing information at that time.^{12,14} In addition, some HCPs may not have training in communication, which can lead to obstacles in effectively conveying diagnoses to patients.¹⁴ HCPs may not identify a patient's need for additional information or emotional support. We recommend developing multidisciplinary education tools for HCPs, including information about best practices for patient communication and assessing the communication needs of patients experiencing distress.

Barriers in communication can also affect caregivers, who often serve as liaisons between the HCP, patient, and family.¹⁸ Difficulties in communication with both patients and their caregivers are further compounded by a lack of easily understandable and distributable information on the disease and treatment options available to patients.¹⁴ Caregivers participating in the roundtable were present at diagnosis and devastated by the news. Based on their experiences, we recommend providing opportunities for education and support to caregivers at diagnosis, as they in turn support patients.

Accessing knowledge needed to make informed treatment decisions can be challenging for patients and caregivers

Successful communication between patients and HCPs and shared decision making are key components of high-quality health care.¹⁴ In a study on decision making in patients with early breast cancer, 83.2% of the 440 patients surveyed reported treatment recommendations made by a provider, while 48.6% reported being asked by a provider for treatment preference.¹⁹ Overall, the level of control that roundtable participants felt they exerted over their treatment decisions varied widely. Some patients felt very in control of their treatment decisions, while others believed that they had minimal or no control. The results reported by patient participants differed from a survey of patients age 60 or older diagnosed with early-stage invasive breast cancer, who reported feeling empowered to undertake treatment decision making based on a high level of support received during the decision-making process. However, this same survey of patients with early-stage breast cancer also revealed that half of participants thought that they were not provided with choices for adjuvant treatment options.²⁰ Similarly, patients participating in the MBC Roundtable who were originally diagnosed with early-stage breast cancer (stages I and III) voiced that they did not fully understand their treatment options at this stage. They reported feeling that their treatment in the early stages was too conservative and expressed that they did not understand the risk of progression to MBC. This perceived lack of information continued after diagnosis of MBC. Patients voiced being positive about pharmaceutical research but concerned that their oncologists may not always be aware of new treatments.

The desire for information about MBC and its treatment led patients to seek information from a wide range of sources, including the care team, other patients, online resources, advocacy organizations, and pharmaceutical companies (Table 1). Their experiences reveal that educational materials from HCPs, pharmaceutical companies, or self-directed resources can help patients become more informed about MBC and treatment options.

Table 1. Sources of information about MBC and its treatment reported by roundtable participants.

Type of Resource	Specific Sources by Type of Information		Considerations for Enhancing Patient Care
	General MBC	Treatment	
Care team	<ul style="list-style-type: none"> • PCPs • Oncologists • Surgeons • NPs 	<ul style="list-style-type: none"> • Oncologists • Surgeons 	<ul style="list-style-type: none"> • Provide consistent information from each member of the care team • Ensure HCPs have up-to-date information about new treatment options
Other patients	<ul style="list-style-type: none"> • In-person support groups • Online support groups • Facebook • Family members • Patient navigators 	<ul style="list-style-type: none"> • In-person support groups (preference) • Online support groups • Facebook groups 	<ul style="list-style-type: none"> • Create support groups focused on the needs of patients with MBC • Educate patients about new treatments for MBC
Online	<ul style="list-style-type: none"> • Google • Health care sites (eg, WebMD) • Breast cancer sites (eg, https://breast-cancer.ca/) 	<ul style="list-style-type: none"> • Google • Congress summaries • Videos and webinars 	<ul style="list-style-type: none"> • Develop trusted resources where patients can find reliable information • Ensure that resources are focused and understandable for patients overwhelmed with information
Advocacy organizations	<ul style="list-style-type: none"> • In-person support groups 	<ul style="list-style-type: none"> • Financial information related to treatment 	<ul style="list-style-type: none"> • Create mechanisms designed to support patients with MBC, in addition to those for patients with early-stage breast cancer
Pharmaceutical companies	<ul style="list-style-type: none"> • N/A 	<ul style="list-style-type: none"> • Product websites • Calling the drug manufacturer • Specific drug information pamphlets and packages 	<ul style="list-style-type: none"> • Have commercials and advertisements that reflect the real-life experiences of patients • Ensure that patients know that they can contact the manufacturer with questions

HCP, health care provider; MBC, metastatic breast cancer; N/A, not applicable; NP, nurse practitioner; PCP, primary care provider.

Like patients, caregivers for patients with breast cancer reported a strong interest in obtaining education about the disease and its treatment.²¹ Although patients drove decision making, caregivers participating in the roundtable noted feeling overwhelmed or untrusting of the information available online. These findings suggest that, in addition to patients, caregivers would benefit from a trusted source of information focused on management of MBC. We recommend developing information geared to caregivers to help them become more educated about MBC so they can better support patients.

Although more than half of patients with MBC report being scared of the unknown, patients with breast cancer also maintain attitudes of commitment, determination, and hope.²² A survey of patients with MBC revealed that 64% of patients were “committed to doing all I could to fight the disease,” and 53% were “determined to treat my advanced breast cancer as aggressively as possible.”²²

Patients in the roundtable voiced a desire to talk about specific fears and issues that they have regarding MBC, but found that most support groups were focused on patients with early breast cancer. We recommend creating mechanisms to support MBC patients, separate from those targeting patients with earlier-stage breast cancer.

Although route of treatment administration, quality of life, and side effects of treatment were identified as important factors in making treatment decisions, long-term survival was the most important factor for many roundtable participants. Some patients also outlined toxicities that could cause them to inquire about switching treatments, including prolonged diarrhea or nausea (that affected their daily routines), visible toxicities (eg, drugs that cause them to lose their hair or have a rash on their faces), and/or high blood

pressure. Similar to the results reported from the roundtable, a survey of patients with MBC identified treatment efficacy, side effects, and factors related to quality of life as important factors in treatment decision making.²³ These findings suggest that providing patients with information about the efficacy and side effects associated with various treatment options would empower them in treatment decision making. We recommend both HCP-delivered and self-directed resources that provide a simple description of the factors that patients are concerned about, to help them make informed decisions about treatment.

Patients Need Support When Starting and Continuing Treatment

After finalizing the treatment decision, patients noted initiation of treatment as another key point in the patient experience where support is needed. They shared that each time they started a new treatment, they were faced with a new set of questions and concerns surrounding efficacy, toxicity, and quality of life. Patients highlighted the need for physical and emotional support in managing challenging side effects and stated the importance of the health care team in reassuring patients about side effect management. Participants also noted the importance of family support. Caregivers or family members were often tasked with recording information from HCPs at each appointment, and, in several cases, patients moved in with family members after diagnosis or during treatment. Caregivers offered physical support in the days after treatments, when patients felt sick or fatigued, in addition to helping patients handle feelings of isolation during treatment. Consistent with these findings, a previous study

also noted that patients with MBC report being anxious about managing the side effects of new breast cancer treatments and about the effects of a new cancer regimen on their lifestyles.²² We recommend helping caregivers and families to support patients during treatments, including education about side effects and emotional support strategies.

Financial burdens can be another cause of distress for patients with cancer,²⁴ and this issue was raised as a concern by roundtable participants. Patients were fearful of reaching the lifetime maximum for insurance payments and not being able to afford their medications. Financial issues have previously been reported to represent a barrier to adherence to therapy for patients with breast cancer, along with logistical issues with accessing treatment, side effects, mistakes with oral regimens, lack of understanding about the treatment, and the quality of the relationship between the patient and the HCP.^{25–27}

Although roundtable participants did not report any current issues with medication adherence, patients did mention that HCPs or pharmaceutical companies could provide support with education about drug interactions; pharmacy and insurance assistance; medication information and reminders, including check-in calls from nurses and/or apps or timers for medication reminders; and mechanisms to organize multiple medications, including easy-to-open pill packs. We recommend ensuring patients and caregivers understand medications and drug interactions, and helping patients with adherence by providing mechanisms for pharmacy and insurance assistance, as well as blister packs or other medication organizers.

Recommendations for the treatment journeys of patients with metastatic breast cancer (MBC).

Recommendation 1: Educate patients about the risk of progression from early-stage breast cancer to MBC, emphasizing how to recognize signs of progression

Recommendation 2: Provide information to health care providers (HCPs) about best practices for communicating with patients and assessing the needs of patients experiencing distress

Recommendation 3: Support and educate caregivers at diagnosis, as they in turn support patients

Recommendation 4: Create HCP-delivered and self-directed educational tools for patients to become more informed about MBC and treatment options

Recommendation 5: Develop trusted informational resources geared toward caregivers to help them become more educated about MBC and treatments

Recommendation 6: Provide support for patients with MBC, separate from mechanisms targeting patients with early-stage breast cancer

Recommendation 7: Help caregivers and families support patients during treatments, including education on side effects and emotional support

Recommendation 8: Develop patient-support tools to help with adherence, including educational resources focused on medications and drug interactions, tools for pharmacy and insurance assistance, and blister packs or other medication organizers

SUMMARY AND LIMITATIONS

Findings from the MBC Roundtable resulted in a total of 8 recommendations developed to target the needs of patients with MBC. Implementation of these recommendations through collaborative partnerships among patients, caregivers, HCPs, advocacy organizations, academic institutions, and pharmaceutical companies could greatly improve the experiences of patients with MBC as they navigate their treatment journeys.

One limitation of this study was the small number of participants (5 women diagnosed with MBC and 3 caregivers). Discussions and recommendations should be further validated in a larger population of women with MBC.

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