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Clinical Trials: Connecting MBC Patients to New Treatment Opportunities

AJ Scheitler, Susan H. Babey, Riti Shimkhada, Beth Glenn, and Ninez A. Ponce

SUMMARY

- Clinical trials are a key part of improving treatment for breast cancer, including metastatic breast cancer (MBC). However, the value of clinical trials for improving racial/ethnic and socioeconomic disparities in care will only be realized if trials include diverse participant samples.
- Barriers to enrollment in trials include poor awareness and lack of user-friendly information about trials, difficulties in accessing trial sites, and lack of clarity about whether or not trial costs are covered by insurance.
- While some policy efforts have been made to address the cost barriers to trial participation, more work can be done to ensure diverse racial/ethnic representation.

In 2019, 30,650 individuals were diagnosed with breast cancer in California, and 4,620 died from the disease.¹ Metastatic breast cancer, also called stage 4 or advanced breast cancer, was the cause of nearly all of these deaths. An estimated 30% of women diagnosed with early-stage breast cancer will go on to develop MBC. The five-year survival rate for MBC is only 27%, compared to 91% for breast cancer that has spread to lymph nodes and 99% for cancer that is confined to the breast.¹

In this fact sheet, we present findings from interviews, discussions, and studies (see boxed section) on insurance-related barriers, and we recommend policy solutions that could improve access to care for patients with MBC.

Progress in treating MBC and reducing disparities in outcomes depends on successful completion of clinical trials with diverse study samples, particularly low-income and racially and ethnically diverse patients. Clinical trials provide access to the latest treatments, which can be critical for MBC patients who may not have many other treatment options.² Many participants in our study expressed an interest in enrolling in a clinical trial but said that they had faced several barriers, including a lack of awareness

about how to enroll; trouble identifying an appropriate trial; lack of accessibility; and confusion or uncertainty about costs, including whether insurance covered the costs.

Challenges Getting Connected to Trials

Lack of access to information about trials. Most (66%) cancer patients who have participated in clinical trials report having initially learned of their trial through one of their providers or via the research staff,

compared to only 6% who learned of their trial through a patient advocacy group.³ In fact, most patients rely on their providers to recommend appropriate clinical trials. However, many providers working in community settings may not have this type of information.

Patients who try to seek information on their own also face challenges. Lack of health literacy is a barrier for some patients. Even patients who said they know what they're looking for in a trial reported that the main portal (clinicaltrials.gov) for identifying trials is not user-friendly. As one study respondent said:

Services that are available for clinicaltrials.gov and all those types of things can be really hard to navigate for a patient.

To address the lack of an accessible, easy-to-navigate central resource and to help MBC patients and their caregivers, the Susan G. Komen Foundation created a helpline to assist with this issue. However, only one respondent in this study was aware of its existence.

Lack of geographic access. Even if a patient can identify an appropriate study, accessibility may be a barrier if the trial site is not local. One of the MBC patients we interviewed who had successfully enrolled in a trial had to travel across the country to Boston to participate, paying her costs out of pocket. Potential costs to the patient, and uncertainty about whether those costs are covered by health insurance, add to the confusion.

Confusion over who pays the costs. While the Affordable Care Act (ACA) requires most private health insurers to cover routine patient care costs for cancer clinical trial participation, many respondents who had participated in clinical trials reported confusion over whether care would be covered

by the clinical trial, by insurance, or by the patient, out of pocket. Fear of those costs may be a significant deterrent to even considering enrolling in a trial, particularly for patients covered by Medicaid. From one respondent:

You know, I was charged for my hospital visits. I was charged for the hospital. I mean, it's okay, I can afford it, but it's not okay, right? It's like, we're doing something for someone, and those costs would be absorbed, and I don't know what they are upfront. I think it really depends on each trial, so there's nothing that's really standardized.

Exclusion of diverse groups. To develop treatments that work for all MBC patients, clinical trials must include participants who represent not only different disease profiles, but also diverse racial and ethnic communities. Black and Latinx populations are underrepresented in cancer clinical trials,⁴ which can perpetuate disparities in cancer outcomes. However, information about trials is not always available in forms that can reach all populations. For example, one patient respondent in our study spoke multiple languages, and while she had a mastery of English, she noted that most resources she found were only in English.

Policy Recommendations

Our legislative scan documented areas where California has made progress and identified areas of need based on our study findings. We recommend that:

- Policymakers and funders invest in programs to increase participation among Black and Latinx patients in clinical trials to help diversify the participant pool.
- Policymakers consider expanding coverage or assistance for noncovered costs associated with trial participation (i.e., travel expenses).

Author Information

AJ Scheitler, EdD, is the director of stakeholder relations at the UCLA Center for Health Policy Research (UCLA CHPR). Susan H. Babey, PhD, is a senior research scientist and co-director of the Chronic Disease Program at UCLA CHPR. Riti Shimkhada, MPH, PhD, is a public administration analyst at UCLA CHPR. Beth Glenn, PhD, is a professor in the Department of Health Policy and Management at the UCLA Fielding School of Public Health. Ninez A. Ponce, MPP, PhD, is a professor at the UCLA Fielding School of Public Health and director of the UCLA CHPR.

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Endnotes

- 1 American Cancer Society. 2020. *Cancer Facts & Figures 2020*. Atlanta, Ga.: American Cancer Society.
- 2 Santa-Maria CA, Gradishar WJ. 2015. Changing Treatment Paradigms in Metastatic Breast Cancer: Lessons Learned. *JAMA Oncology* 1(4):528-534; quiz 549.
- 3 American Cancer Society Cancer Action Network. 2018. *Barriers to Patient Enrollment in Therapeutic Clinical Trials for Cancer: A Landscape Report*. Washington, D.C.: American Cancer Society Cancer Action Network.
- 4 Loree JM, Anand S, Dasari A, Unger JM, Gothwal A, Ellis LM, Varadhachary G, Kopetz S, Overman MJ, Raghav K. 2019. Disparity of Race Reporting and Representation in Clinical Trials Leading to Cancer Drug Approvals From 2008 to 2018. *JAMA Oncology* 5(10):e191870. doi:10.1001/jamaoncol.2019.1870. Epub ahead of print. PMID: 31415071; PMCID: PMC6696743.

Addressing Barriers to Metastatic Breast Cancer Care in California: Levers for Policy Change

Metastatic breast cancer (MBC) occurs all across the United States, but differences in health care systems, health insurance products, and population characteristics create state-level differences in the experiences of patients. While there are national standards and laws governing different aspects of care for MBC patients, state-level policies still have significant impact.

The findings contained in this fact sheet are drawn from a study by the UCLA Center for Health Policy Research and the UCLA Center for Cancer Prevention and Control Research on the barriers to metastatic breast cancer care in California. The study report synthesized information collected by listening to patients and to both clinical and non-clinical caregivers, as well as by accessing published research, the grey literature, and Twitter chat.

Read the full report:
<https://healthpolicy.ucla.edu/publications/search/pages/detail.aspx?PubID=2101>



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